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**COMMITTEE OF EXPERTS ON THE
TRANSPORT OF DANGEROUS GOODS AND ON THE
GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION
AND LABELLING OF CHEMICALS**

**REPORT OF THE COMMITTEE OF EXPERTS ON THE TRANSPORT OF
DANGEROUS GOODS AND ON THE GLOBALLY HARMONIZED SYSTEM OF
CLASSIFICATION AND LABELLING OF CHEMICALS ON ITS FOURTH SESSION**
(Geneva, 12 December 2008)

Addendum

Annex III

Amendments to the second revised edition of the Globally Harmonized System
of Classification and labelling of Chemicals (GHS) (ST/SG/AC.10/30/Rev.2)

PART 1

Chapter 1.1

- 1.1.1.1 In the first and fourth sentences, replace “chemical products” with “chemicals”.
- 1.1.1.2 In the first sentence, replace “product” with “chemical”.
- 1.1.1.6 In (b), replace “chemical elements and compounds and mixtures thereof” with “substances and mixtures”.
- In (d), delete “chemical” before “safety data sheets”.
- 1.1.2.5 (a) At the beginning of the first sentence of sub-paragraph (ii) delete “and chemical products”.
- In the first sentence of sub-paragraph (iii) replace “products” with “chemicals”.

1.1.2.6.2.1 At the end of the first sentence, delete “or chemical product”.

1.1.3.1.1 In the first sentence, delete “chemical” before “substances”.

Chapter 1.2

Amend as follows the definitions hereafter:

“*Aspiration*” delete “product”.

“*Carcinogen*” Amend the beginning to read as follows: “means a substance or a mixture which”.

“*Contact sensitizer*” *Delete the definition*

“*NOEC*” Amend to read as follows:

“*NOEC (No observed effect concentration)* means the test concentration immediately below the lowest tested concentration with statistically significant adverse effect. The NOEC has no statistically significant adverse effect compared to the control.”.

“*Oxidizing gas*” Add the following note after the definition:

NOTE: “Gases which cause or contribute to the combustion of other material more than air does” means pure gases or gas mixtures with an oxidizing power greater than 23.5% as determined by a method specified in ISO 10156:1996 or 10156-2:2005”.

“*Skin sensitizer*” Delete the last sentence.

“*SPR*” Delete the definition.

Insert, in alphabetical order, the following new definitions:

“*EC_x* means the concentration associated with x% response.

Montreal Protocol means the Montreal Protocol on Substances that Deplete the Ozone Layer as either adjusted and/or amended by the Parties to the Protocol.

Ozone Depleting Potential (ODP) means an integrative quantity, distinct for each halocarbon source species, that represents the extent of ozone depletion in the stratosphere expected from the halocarbon on a mass-for-mass basis relative to CFC-11. The formal definition of ODP is the ratio of integrated perturbations to total ozone, for a differential mass emission of a particular compound relative to an equal emission of CFC-11.”.

Chapter 1.3

- 1.3.2.1.1 Amend the first sentence to read as follows: “The GHS applies to pure substances and their dilute solutions and to mixtures”.
- 1.3.2.4.2 In the first and third sentences delete “chemical” before “substance”.

Chapter 1.4

- 1.4.8.3 In sub-paragraph (a), in the first sentence, replace “chemicals” with “substances”.
- In sub-paragraph (d), replace “hazardous chemical or a chemical mixture” with “hazardous substance or mixture”.
- 1.4.10.3 Replace the symbol under “Environment” with the following one:



- 1.4.10.5.3.3 Amend to read as follows:

“1.4.10.5.3.3 Precedence for allocation of hazard statements

All assigned hazard statements should appear on the label, except where otherwise provided in this sub-section. The competent authority may specify the order in which they appear.

However, to avoid evident duplication or redundancy in the information conveyed by hazard statements, the following precedence rules may be applied:

- (a) If the statement H410 “Very toxic to aquatic life with long lasting effects” is assigned, the statement H400 “Very toxic to aquatic life” may be omitted;
- (b) If the statement H411 “Toxic to aquatic life with long lasting effects” is assigned, the statement H401 “Toxic to aquatic life” may be omitted;
- (c) If the statement H412 “Harmful to aquatic life with long lasting effects” is assigned, the statement H402 “Harmful to aquatic life” may be omitted;

- (d) If the statement H314 “Causes severe skin burns and eye damage” is assigned, the statement H318 “Causes serious eye damage” may be omitted.

Competent authorities may decide whether to require use of the above precedence rules, or to leave the choice to the manufacturer/supplier.

Table A3.1.2 in Annex 3 includes specified combinations of hazard statements. Where a combined hazard statement is indicated, the competent authority may specify whether the combined hazard statement or the corresponding individual statements should appear on the label, or may leave the choice to the manufacturer/supplier.”.

1.4.10.5.4.4 Add a new paragraph to read as follows:

“1.4.10.5.4.4 Labelling of small packagings

The general principles that should underpin labelling of small packagings are:

- (a) All the applicable GHS label elements should appear on the immediate container of a hazardous substance or mixture where possible;
- (b) Where it is impossible to put all the applicable label elements on the immediate container itself, other methods of providing the full hazard information should be used in accordance with the definition of “Label” in the GHS. Factors influencing this include *inter alia*:
 - (i) the shape, form or size of the immediate container;
 - (ii) the number of label elements to be included, particularly where the substance or mixture meets the classification criteria for multiple hazard classes;
 - (iii) the need for label elements to appear in more than one official language;
- (c) Where the volume of a hazardous substance or mixture is so low and the supplier has data demonstrating, and the competent authority has determined, that there is no likelihood of harm to human health and/or the environment, then the label elements may be omitted from the immediate container;
- (d) Competent authorities may allow certain label elements to be omitted from the immediate container for certain hazard

classes/categories where the volume of the substance or mixture is below a certain amount;

- (e) Some labelling elements on the immediate container may need to be accessible throughout the life of the product, e.g. for continuous use by workers or consumers.”

1.4.10.5.5.1 In the last sentence of the second paragraph, delete “chemical” before “mixtures”.

Chapter 1.5

1.5.1.1 In the first sentence, delete “chemical” before “substance”.

PART 2

Chapter 2.1

Figure 2.1.3 Replace current figure 2.1.3 with the following:

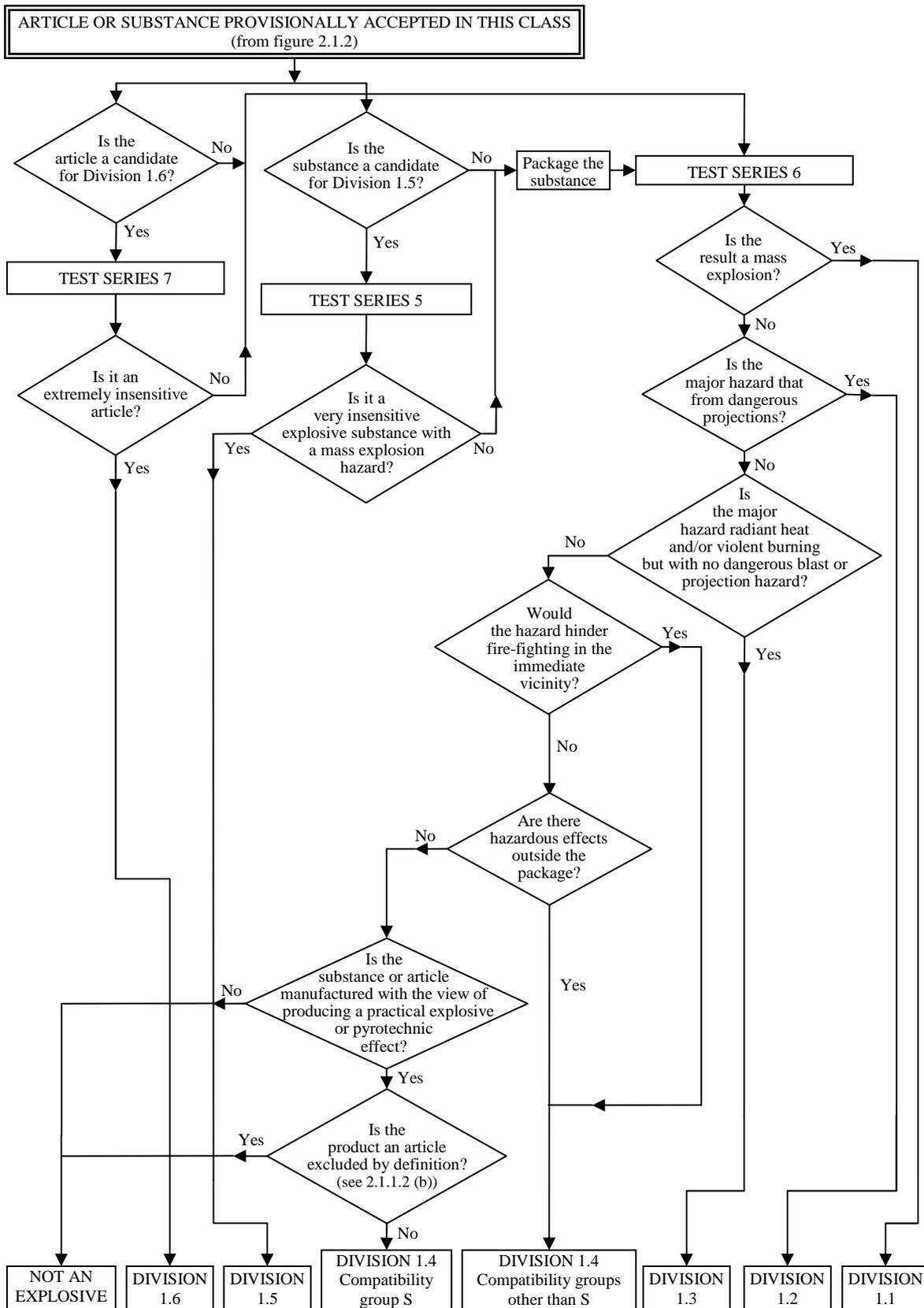


Figure 2.1.4 Amend as follows:

- Amend the title to read as follows: "Procedure for the classification of ammonium nitrate emulsion, suspension or gel (ANE)".
- Amend the text in the last box on the left hand side to read as follows: "ANE substance/mixture shall be classified as a Category 2 oxidizing liquid or a Category 2 oxidizing solid; (Chapters 2.13 and 2.14)".

2.1.4.2.1 In the NOTE, add the following new sentence at the end:

“For organic substances and mixtures of organic substances with a decomposition energy of 800 J/g or more, tests 1 (a) and 2 (a) need not be performed if the outcome of the ballistic mortar Mk.III d test (F.1), or the ballistic mortar test (F.2) or the BAM Trauzl test (F.3) with initiation by a standard No.8 detonator (see Appendix 1 to the *Manual of Tests and Criteria*) is “no”. In this case, the results of test 1 (a) and 2 (a) are deemed to be “-”.”.

Chapter 2.2

2.2.2 Amend NOTE 2 under Table 2.2.1 to read as follows:

“NOTE 2: Aerosols should not be classified as flammable gases. See Chapter 2.3.”

Chapter 2.3

2.3.2.1 Replace "NOTE" with "NOTE 1" and add a new NOTE 2 to read as follows:

"NOTE 2: Flammable aerosols do not fall additionally within the scope of chapters 2.2 (flammable gases), 2.6 (flammable liquids) or 2.7 (flammable solids)."

2.3.2.2 Add a new Note at the end to read as follows:

"NOTE: Aerosols not submitted to the flammability classification procedures in this Chapter should be classified as extremely flammable (Category 1)."

Chapter 2.4

2.4.1 Add the following note after the definition of “oxidizing gas”:

“NOTE: “Gases which cause or contribute to the combustion of other material more than air does” means pure gases or gas mixtures with an oxidizing power greater than 23.5% as determined by a method specified in ISO 10156:1996 or 10156-2:2005.”

Consequential amendment: See amendments to chapter 1.2.

2.4.2 Delete the note after table 2.4.1.

Chapter 2.6

2.6.2 In Note 2 to table 2.6.1, insert "and not more than 60 °C" after "more than 35 °C".

Add a new NOTE 4 to read as follows:

“NOTE 4: Aerosols should not be classified as flammable liquids. See Chapter 2.3.”

2.6.4.2.2 At the end of the introductory text preceding sub-paragraphs (a) to (d) replace “below, is at least 5 °C greater than the relevant classification criterion and provided that:” with “below, is at least 5 °C⁴ greater than the relevant classification criterion (23 °C and 60 °C, respectively) and provided that:”.

In (b), replace “flash point (closed-cup as given in 2.6.4.2.5 below)” with “lower explosion limit” and add “as well as a method for calculating the lower explosion limit of the mixture;” at the end, after the text between brackets.

Amend (c) to read as follows:

“(c) The temperature dependence of the saturated vapour pressure and of the activity coefficient is known for each ingredient as present in the mixture;”

Amend the text of footnote 3 to read as follows:

“³ Up to now, the calculation method is validated for mixtures containing up to six volatile components. These components may be flammable liquids like hydrocarbons, ethers, alcohols, esters (except acrylates), and water. It is however not yet validated for mixtures containing halogenated, sulphurous, and/or phosphoric compounds as well as reactive acrylates.”

Insert a new footnote “4” to read as follows:

“⁴ If the calculated flash point is less than 5°C greater than the relevant classification criterion, the calculation method may not be used and the flash point should be determined experimentally.”

2.6.4.2.5 Amend the introductory sentence before the list of standards to read as follows:

“The following methods for determining the flash point of flammable liquids should be used:”.

Under “International Standards” insert “ISO 2719” and “ISO 13736” before “ISO 3679”.

Under “National Standards”:

- Amend the address of the “*Association française de normalisation*” (AFNOR) to read as follows: “11, rue de Pressensé. 93571 La Plaine Saint-Denis Cedex”.

- Delete the references to the British Standards Institute standards (from “*British Standards Institute*” to “BS 2000 Part 170”);
- In the list of *Deutsches Institut für Normung* standards, replace “*Burggraffenst 6*” with “*Burggrafenstr. 6*” in the address and delete the two last standards (DIN 51758 and DIN 53213).

2.6.4.2.6 Add a new 2.6.4.2.6 to read as follows:

“2.6.4.2.6 The following methods for determining the initial boiling point of flammable liquids should be used:

International standards:

ISO 3924

ISO 4626

ISO 3405

National standards:

American Society for Testing Materials International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, USA 19428-2959:

ASTM D86-07a “Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure”

ASTM D1078-05 “Standard Test Method for Distillation Range of Volatile Organic Liquids”

Further acceptable methods:

Method A.2 as described in Part A of the Annex to Commission Regulation (EC) No 440/2008⁵”

Add a new footnote 5 to read as follows:

“⁵ *Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Official Journal of the European Union, No. L142 of 31.05.2008, p1-739 and No. L143 of 03.06.2008, p.55)*”.

Chapter 2.7

2.7.2.4 Add a new NOTE 2 under Table 2.7.1 to read as follows:

“**NOTE 2:** *Aerosols should not be classified as flammable solids. See Chapter 2.3.*”

Current “**NOTE**” becomes “**NOTE 1**”.

Chapter 2.11

2.11.1 Amend the NOTE to read as follows:

"NOTE: Self-heating of a substance or mixture is a process where the gradual reaction of that substance or mixture with oxygen (in air) generates heat. If the rate of heat production exceeds the rate of heat loss, then the temperature of the substance or mixture will rise which, after an induction time, may lead to self-ignition and combustion."

Table 2.11.1 In NOTE 2, last sentence, replace “spontaneous ignition temperature” with “self-ignition temperature”.

PART 3

Chapter 3.1

3.1.2.1 At the beginning of the first sentence, replace “Chemicals” with “Substances”.

Table 3.1.1 Replace note (a) with the following new notes (a) and (b) and rename current notes (b) to (f) as notes (c) to (g):

“(a) The acute toxicity estimate (ATE) for the classification of a substance is derived using the LD₅₀/LC₅₀ where available;

(b) The acute toxicity estimate (ATE) for a substance in a mixture is derived using:

(i) the LD₅₀/LC₅₀ where available; otherwise,

(ii) the appropriate conversion value from Table 3.1.2 that relates to the results of a range test; or

(iii) the appropriate conversion value from Table 3.1.2 that relates to a classification category;”.

Consequential amendments: In the column under “Exposure route”, replace “Note (a)” with “Notes (a), (b)”.

In note (e) (former (d)), at the beginning of the first and second sentence, replace “chemicals” with “substances”.

3.1.2.5 At the beginning of the first sentence, replace “chemicals” with “substances”.

In the text of footnote 1 related to this paragraph, replace “Note (f)” with “note (g)”.

3.1.3.2 Amend to read as follows:

“Classification of mixtures for acute toxicity can be carried out for each route of exposure, but is only needed for one route of exposure as long as this route is followed (estimated or tested) for all ingredients and there is no relevant evidence to suggest acute toxicity by multiple routes. When there is relevant evidence of toxicity by multiple routes of exposure, classification is to be conducted for all appropriate routes of exposure. All available information should be considered. The pictogram and signal word used should reflect the most severe hazard category and all relevant hazard statements should be used.”

3.1.3.3 Add two new sub-paragraphs c) and d) to read as follows:

“(c) If the converted acute toxicity point estimates for all ingredients of a mixture are within the same category, then the mixture should be classified in that category.

(d) When only range data (or acute toxicity hazard category information) are available for ingredients in a mixture, they may be converted to point estimates in accordance with Table 3.1.2 when calculating the classification of the new mixture using the formulas in 3.1.3.6.1 and 3.1.3.6.2.3.”

Table 3.1.2 In the title replace “for classification for the respective routes of exposure” with “for use in the formulas for the classification of mixtures.”

3.1.3.5.1 In the first sentence, insert “both” before “the individual ingredients”.

3.1.3.5.2 In the first sentence of the first paragraph:

- amend the beginning to read “If a tested mixture”;
- replace “the new mixture may” with “the new diluted mixture may”; and
- insert “tested” after “original” at the end of the sentence.

Delete the second paragraph (“If a mixture is diluted...bodyweight.”).

3.1.3.5.3 In the first sentence:

- replace “one production batch” with “a tested production batch”;
- delete “complex”;
- replace “another production batch” with “another untested production batch”;
- replace “and produced by” with “when produced by”, and
- replace “toxicity of the batch” with “toxicity of the untested batch”.

In the last sentence insert “a” before “new classification”.

3.1.3.5.4 Insert “tested” before “mixture” (twice) at the beginning of the sentence and replace, at the end, “new mixture” with “resulting untested mixture” at the end.

3.1.3.5.5 Amend to read as follows:

“For three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are in the same toxicity category, and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be in the same toxicity category as A and B.”.

3.1.3.5.6 In the sentence after sub-paragraphs (a) to (d):

- amend the beginning of the sentence to read: “If mixture (i) or (ii)”;
- replace “mixture (ii)” with “the other mixture” at the end of the sentence.

3.1.3.6.1 Amend sub-paragraph (c) and the first sentence after it to read as follows:

“(c) Ignore ingredients if the data available are from a limit dose test (at the upper threshold for Category 4 for the appropriate route of exposure as provided in Table 3.1.1) and do not show acute toxicity.

Ingredients that fall within the scope of this paragraph are considered to be ingredients with a known acute toxicity estimate (ATE). See note (b) to Table 3.1.1 and paragraph 3.1.3.3 for appropriate application of available data to the equation below, and paragraph 3.1.3.6.2.3.”.

The remainder of the paragraph (introductory sentence, sub-paragraphs (a) and (b) and the formula and the sentence immediately before it) remains unchanged.

3.1.3.6.2.1 (a) Amend the text of footnote 2 related to this sub-paragraph to read as follows:

“² When mixtures contain ingredients that do not have acute toxicity data for each route of exposure, acute toxicity estimates may be extrapolated from the available data and applied to the appropriate routes (see 3.1.3.2). However, competent authorities may require testing for a specific route. In those cases, classification should be performed for that route based upon the competent authority's requirement.”.

3.1.3.6.2.2 Replace “without any useable information at all” with “without any useable information for classification”.

Chapter 3.2

3.2.2.2 In the first sentence, replace “chemicals” with “substances” and in the seventh sentence replace “chemical” with “substance”.

Figure 3.2.1 For steps 2a and 2b, under “Parameter” delete “or structure-property relationships^(b)”.

Consequential amendments: Delete Note (b) to figure 3.2.1 and rename remaining notes and references to them in figure 3.2.1 accordingly.

3.2.3.2.1 In the first sentence, insert “both” before “the individual ingredients”.

3.2.3.2.2 In the first sentence:

- amend the beginning to read “If a tested mixture”;
- replace “the new mixture may” with “the new diluted mixture may”; and
- insert “tested” after “original” at the end of the sentence.

3.2.3.2.3 In the first sentence:

- replace “one production batch” with “a tested production batch”;
- delete “complex”;
- replace “another production batch” with “another untested production batch”;
- replace “and produced by” with “when produced by”, and
- replace “toxicity of the batch” with “toxicity of the untested batch”.

In the last sentence insert “a” before “new classification”.

3.2.3.2.4 Replace (twice) “a more concentrated mixture” with “the more concentrated untested mixture”.

3.2.3.2.5 Amend to read as follows:

“For three mixtures (A, B, and C) with identical ingredients, where mixtures A and B have been tested and are in the same irritation/corrosion toxicity category, and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be in the same irritation/corrosion category as A and B.”.

3.2.3.2.6 In the sentence after sub-paragraphs (a) to (d):

- amend the beginning of the sentence to read “If mixture (i) or (ii)”;
- replace “mixture (ii)” with “the other mixture”; and
- insert “hazard” before “category”.

Chapter 3.3

3.3.2.1 In the second sentence, delete “or structure-property relationships (SPR)”.

3.3.2.4 In the first sentence, replace “chemicals” with “substances”.

3.3.2.5 In the first sentence, replace “chemical” with “substance”.

Figure 3.3.1 For steps 2a, 2b and 2c, under “Parameter” replace “Structure activity relationships/Structure property relationships (SAR/SPR)” with “Structure activity relationships (SAR)”.

In the notes to Figure 3.3.1:

- Step 1a/b: at the beginning of the second sentence, replace “chemical” with “substance”;
- “Step 2a/b/c”: delete “/SPR (Structure Property Relationships)” in the first sentence and “/SPR” in the second and third sentences.

3.3.2.9 In the sentence after table 3.3.2, replace “chemicals” with “substances”.

3.3.3.2.1 In the first sentence, insert “both” before “the individual ingredients”.

3.3.3.2.2 In the first sentence:

- amend the beginning to read “If a tested mixture”;
- replace “the new mixture may” with “the new diluted mixture may”; and
- insert “tested” after “original” at the end of the sentence.

3.3.3.2.3 In the first sentence:

- replace “one production batch” with “a tested production batch”;
- delete “complex”;
- replace “another production batch” with “another untested production batch”;
- replace “and produced by” with “when produced by”, and
- replace “toxicity of the batch” with “toxicity of the untested batch”.

In the last sentence insert “a” before “new classification”.

3.3.3.2.4 Replace (twice) “a more concentrated mixture” with “the more concentrated untested mixture”.

3.3.3.2.5 Amend to read as follows:

“For three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are in the same irritation/serious eye damage toxicity category, and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be in the same irritation/serious eye damage category as A and B.”.

3.3.3.2.6 In the last sentence after the sub-paragraphs:

- amend the beginning of the sentence to read “If mixture (i) or (ii)”;
- replace “mixture (ii)” with “the other mixture”; and
- insert “hazard” before “category”.

Chapter 3.4

3.4.1.1 In the French version, replace “sensibilisant de contact” par “sensibilisant cutané” (the amendment does not apply to the English version).

3.4.1.5 Add the following new paragraph:

“3.4.1.5 The hazard class “respiratory or skin sensitization” is differentiated into:

- (a) Respiratory sensitization; and
- (b) Skin sensitization”.

3.4.2.1.1 Amend to read as follows:

“3.4.2.1.1 *Hazard categories*

3.4.2.1.1.1 Respiratory sensitizers shall be classified in Category 1 where sub-categorization is not required by a competent authority or where data are not sufficient for sub-categorization.

3.4.2.1.1.2 Where data are sufficient and where required by a competent authority, a refined evaluation according to 3.4.2.1.1.3 allows the allocation of respiratory sensitizers into sub-category 1A, strong sensitizers, or sub-category 1B for other respiratory sensitizers.

3.4.2.1.1.3 Effects seen in either humans or animals will normally justify classification in a weight of evidence approach for respiratory sensitizers. Substances may be allocated to one of the two sub-categories 1A or 1B using a weight of evidence approach in accordance with the criteria given in Table 3.4.1 and on the basis of reliable and good quality evidence from human cases or epidemiological studies and/or observations from appropriate studies in experimental animals.

Table 3.4.1: Hazard category and sub-categories for respiratory sensitizers

CATEGORY 1:	Respiratory sensitizer
	A substance is classified as a respiratory sensitizer (a) if there is evidence in humans that the substance can lead to specific respiratory hypersensitivity and/or (b) if there are positive results from an appropriate animal test ² .
Sub-category 1A:	Substances showing a high frequency of occurrence in humans; or a probability of occurrence of a high sensitization rate in humans based on animal or other tests ² . Severity of reaction may also be considered.
Sub-category 1B:	Substances showing a low to moderate frequency of occurrence in humans; or a probability of occurrence of a low to moderate sensitization rate in humans based on animal or other tests ² . Severity of reaction may also be considered.”

Add the following footnote 2:

“² At present, recognized and validated animal models for the testing of respiratory hypersensitivity are not available. Under certain circumstances, data from animal studies may provide valuable information in a weight of evidence assessment.”

3.4.2.1.2.1 In the first sentence, replace “induce” with “lead to”.

3.4.2.1.3 Amend the text of related footnote 2 to read as follows:

“² At present, recognized and validated animal models for the testing of respiratory hypersensitivity are not available. Under certain circumstances, data from animal studies may provide valuable information in a weight of evidence assessment.”

3.4.2.2.1 Amend to read as follows:

“3.4.2.2.1 *Hazard categories*

3.4.2.2.1.1 Skin sensitizers shall be classified in Category 1 where sub-categorization is not required by a competent authority or where data are not sufficient for sub-categorization.

3.4.2.2.1.2 Where data are sufficient and where required by a competent authority, a refined evaluation according to 3.4.2.2.1.3 allows the allocation of skin sensitizers into sub-category 1A, strong sensitizers, or sub-category 1B for other skin sensitizers.

3.4.2.2.1.3 Effects seen in either humans or animals will normally justify classification in a weight of evidence approach for skin sensitizers as described in 3.4.2.2.2. Substances may be allocated to one of the two sub-categories 1A or 1B using a weight of evidence approach in accordance with the criteria given in Table 3.4.2 and on the basis of reliable and good quality evidence from human cases or epidemiological studies and/or observations from appropriate studies in experimental animals according to the guidance values provided in 3.4.2.2.2.1 and 3.4.2.2.3.2 for sub-category 1A and in 3.4.2.2.2.2 and 3.4.2.2.3.3 for sub-category 1B.

Table 3.4.2: Hazard category and sub-categories for skin sensitizers

CATEGORY 1:	Skin sensitizer
	A substance is classified as a skin sensitizer (a) if there is evidence in humans that the substance can lead to sensitization by skin contact in a substantial number of persons, or (b) if there are positive results from an appropriate animal test.
Sub-category 1A:	Substances showing a high frequency of occurrence in humans and/or a high potency in animals can be presumed to have the potential to produce significant sensitization in humans. Severity of reaction may also be considered.
Sub-category 1B:	Substances showing a low to moderate frequency of occurrence in humans and/or a low to moderate potency in animals can be presumed to have the potential to produce sensitization in humans. Severity of reaction may also be considered.

3.4.2.2.2 Human evidence

3.4.2.2.2.1 Human evidence for sub-category 1A can include:

- (a) positive responses at $\leq 500 \mu\text{g}/\text{cm}^2$ (HRIPT, HMT – induction threshold);
- (b) diagnostic patch test data where there is a relatively high and substantial incidence of reactions in a defined population in relation to relatively low exposure;
- (c) other epidemiological evidence where there is a relatively high and substantial incidence of allergic contact dermatitis in relation to relatively low exposure.

3.4.2.2.2.2 Human evidence for sub-category 1B can include:

- (a) positive responses at $> 500 \mu\text{g}/\text{cm}^2$ (HRIPT, HMT – induction threshold);
- (b) diagnostic patch test data where there is a relatively low but substantial incidence of reactions in a defined population in relation to relatively high exposure;
- (c) other epidemiological evidence where there is a relatively low but substantial incidence of allergic contact dermatitis in relation to relatively high exposure.”

3.4.2.2.2 to 3.4.2.2.3 Current paragraphs 3.4.2.2.2 to 3.4.2.2.3 become new paragraphs 3.4.2.2.4 to 3.4.2.2.4.4.

3.4.2.2.4 and 3.4.2.2.4.1 Current paragraphs 3.4.2.2.4 and 3.4.2.2.4.1 become new paragraphs 3.4.2.2.3 and 3.4.2.2.3.1.

Delete current paragraphs 3.4.2.2.4.2 and 3.4.2.2.4.3.

3.4.2.2.3.1 (former 3.4.2.2.4.1) Amend the beginning of the first sentence to read as follows: “For Category 1, when an adjuvant type test method...”;

Insert the following new third sentence:

“For Category 1, a stimulation index of three or more is considered a positive response in the local lymph node assay.”.

Delete the last sentence (“In case of...guinea pig test”).

3.4.2.2.3.2 and 3.4.2.2.3.3 Insert two new paragraphs to read as follows:

“3.4.2.2.3.2 Animal test results for sub-category 1A can include data with values indicated in Table 3.4.3 below:

Table 3.4.3: Animal test results for sub-category 1A

Assay	Criteria
Local lymph node assay	EC3 value \leq 2%
Guinea pig maximisation test	\geq 30% responding at \leq 0.1% intradermal induction dose <u>or</u> \geq 60% responding at $>$ 0.1% to \leq 1% intradermal induction dose
Buehler assay	\geq 15% responding at \leq 0.2% topical induction dose <u>or</u> \geq 60% responding at $>$ 0.2% to \leq 20% topical induction dose

3.4.2.2.3.3 Animal test results for sub-category 1B can include data with values indicated in Table 3.4.4 below:

Table 3.4.4: Animal test results for sub-category 1B

Assay	Criteria
Local lymph node assay	EC3 value $>$ 2%
Guinea pig maximisation test	\geq 30% to $<$ 60% responding at $>$ 0.1% to \leq 1% intradermal induction dose <u>or</u> \geq 30% responding at $>$ 1% intradermal induction dose
Buehler assay	\geq 15% to $<$ 60% responding at $>$ 0.2% to \leq 20% topical induction dose <u>or</u> \geq 15% responding at $>$ 20% topical induction dose

3.4.2.2.4.1 (former 3.4.2.2.2.1) At the end of in the introductory sentence insert “using a weight of evidence approach:” after “any or all of the following”;

Add a new sub-paragraph (f) to read as follows: “(f) Severity of reaction may also be considered”.

3.4.2.2.4.2 (former 3.4.2.2.2.2) Delete the first sentence.

In the fourth sentence, replace “contact sensitization” with “skin sensitization”.

Add the following sentence at the end of the paragraph:

“For both animal and human data, consideration should be given to the impact of vehicle.”

3.4.2.2.4.3 (former 3.4.2.2.2.3) In the first sentence, insert a comma after “met” and replace “contact sensitizer” with “skin sensitizer”. In the second sentence, replace “contact sensitization” with “skin sensitization”.

In sub-paragraph (c), replace “3.4.2.2.4.1” with “3.4.2.2.3”

3.4.2.2.4.4 (former 3.4.2.2.3) In the first paragraph replace “contact sensitizers” with “skin sensitizers” (twice).

3.4.3.1 Replace the last sentence with the following:

“(For special labelling required by some competent authorities, see the note to Table 3.4.5 of this chapter and 3.4.4.2).

3.4.3.2.1 In the first sentence, insert “both” before “the individual ingredients”.

3.4.3.2.2 In the first sentence:

- amend the beginning to read “If a tested mixture”;
- replace “the new mixture may” with “the new diluted mixture may”; and
- insert “tested” after “original” at the end of the sentence.

3.4.3.2.3 In the first sentence:

- replace “one production batch” with “a tested production batch”;
- delete “complex”;
- replace “another production batch” with “another untested production batch”;
- replace “and produced by” with “when produced by”, and
- replace “sensitization of the batch” with “sensitization potential of the untested batch”

In the last sentence insert “a” before “new classification”.

3.4.3.2.4 and 3.4.3.2.5 Insert the following new paragraphs:

“3.4.3.2.4 Concentration of mixtures of the highest sensitizing category/sub-category

If a tested mixture is classified in Category 1 or sub-category 1A, and the concentration of the ingredients of the tested mixture that are in Category 1 and sub-category 1A is increased, the resulting untested mixture should be classified in Category 1 or sub-category 1A without additional testing.

3.4.3.2.5 Interpolation within one category/sub-category

For three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are in the same category/sub-category, and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be in the same category/sub-category as A and B.”

Current paragraphs 3.4.3.2.4 and 3.4.2.3.5 become new paragraphs 3.4.3.2.6 and 3.4.3.2.7 respectively.

3.4.3.2.6 (former 3.4.3.2.4) In the sentence after sub-paragraphs (a) to (e):

- amend the beginning to read: “If mixture (i) or (ii)”;
- replace “mixture (ii)” with “the other mixture”.

3.4.3.3 In the paragraph before the table, replace “Table 3.4.1” with “Table 3.4.5”;

Replace the entire table and its six notes with a new table and a single note , as follows:

“Table 3.4.5: Cut-off values/concentration limits of ingredients of a mixture classified as either respiratory sensitizers or skin sensitizers that would trigger classification of the mixture

Ingredient classified as:	Cut-off values/concentration limits triggering classification of a mixture as:		
	Respiratory sensitizer Category 1		Skin sensitizer Category 1
	Solid/Liquid	Gas	All physical states
Respiratory sensitizer Category 1	≥ 0.1% (see note)	≥ 0.1% (see note)	
	≥ 1.0 %	≥ 0.2%	
Respiratory sensitizer Sub-category 1A	≥ 0.1%	≥ 0.1%	
Respiratory sensitizer Sub-category 1B	≥ 1.0 %	≥ 0.2%	

Ingredient classified as:	Cut-off values/concentration limits triggering classification of a mixture as:		
	Respiratory sensitizer Category 1		Skin sensitizer Category 1
	Solid/Liquid	Gas	All physical states
Skin sensitizer Category 1			≥ 0.1% (see note)
			≥ 1.0%
Skin sensitizer Sub-category 1A			≥ 0.1%
Skin sensitizer Sub-category 1B			≥ 1.0%

NOTE : Some competent authorities may require SDS and/or supplemental labelling only, as described in 3.4.4.2 for mixtures containing a sensitizing ingredient at concentrations between 0.1 and 1.0% (or between 0.1 and 0.2% for a gaseous respiratory sensitizer). While the current cut-off values reflect existing systems, all recognize that special cases may require information to be conveyed below that level.”

3.4.4.1 In the last sentence, replace “Table 3.4.2” with “Table “3.4.6”.

In the new Table 3.4.6, add “and sub-categories 1A and 1B” after “Category 1” in the heading of the two last columns.

3.4.4.2 In the first sentence, replace “Table 3.4.1” with “Table 3.4.5”.

Amend the second sentence to read as follows:

“To protect these individuals, certain authorities may choose to require the name of the ingredients as a supplemental label element whether or not the mixture as a whole is classified as sensitizer.”

Delete the last sentence (“Others may choose...Table 3.4.1”).

3.4.5.1 Add a reference to a new footnote 6 in the first box for “Category 1” on the right hand side, as follows: “Category 1⁶”.

Add a new footnote “6” to read as follows: “⁶ See 3.4.2.1.1 for details on use of Category 1 sub-categories.”

In the last but one box on the left hand side, delete “(see 3.4.3.3)” (twice) and insert the following sentence at the end, below sub-paragraph (d): “(See 3.4.3.3 and Table 3.4.5 for explanation and guidance)”.

3.4.5.2 “Add a reference to a new footnote 7 in the first box from the top for “Category 1”, as follows: “Category 1⁷”

Add a new footnote “7” to read as follows: “⁷ See 3.4.2.2.1 for details on use of Category 1 sub-categories.”.

In the central box, replace “3.4.2.2.2” with “3.4.2.2.4” in sub-paragraph (b).

In the last but one box on the left, delete the reference into brackets and insert at the bottom of the box below sub-paragraph (b): “(See 3.4.3.3 and Table 3.4.5 for explanation and guidance)”.

Chapter 3.5

3.5.2.3 In the first sentence replace “chemicals” with “substances” and in the second sentence delete “chemical”.

Figure 3.5.1 Replace “Chemicals” with “Substances” (5 times).

3.5.2.10 In the last sentence, replace “chemical” with “substance”.

3.5.3.2.1 In the first sentence, insert “both” before “the individual ingredients”.

3.5.3.2.2 In the first sentence:

- amend the beginning to read “If a tested mixture”;
- replace “the new mixture may” with “the new diluted mixture may”; and
- insert “tested” after “original” at the end of the sentence.

3.5.3.2.3 In the first sentence:

- replace “one production batch” with “a tested production batch”;
- delete “complex”;
- replace “another production batch” with “another untested production batch”;
- replace “commercial product produced by and under the control” with “commercial product, when produced by or under the control”; and
- replace “potential of the batch” with “potential of the untested batch”.

3.5.3.2.4 In the last sentence after the sub-paragraphs:

- amend the beginning of the sentence to read “If mixture (i) or (ii)”;
- replace “mixture (ii)” with “the other mixture”; and
- insert “hazard” before “category”.

Chapter 3.6

3.6.1 In the first paragraph, amend the beginning of the first sentence to read as follows: “The term *carcinogen* denotes a substance or a mixture which ...” and in the second sentence insert “and mixtures” after “substances”.

Amend the second paragraph to read as follows:

“Classification of a substance or mixture as posing a carcinogenic hazard is based on its inherent properties and does not provide information on the level of the human cancer risk which the use of the substance or mixture may represent.”.

3.6.2.1 In the first sentence delete “chemical” before “substances”.

Figure 3.6.1 Replace “chemical” with “substance” (7 times).

3.6.2.2 Replace “chemicals” with “substances”.

3.6.2.3 Replace “chemicals” with “substances”.

3.6.2.5.2 (g) Replace “chemical(s)” with “substance(s)”.

3.6.2.5.3 Replace “chemical” with “substance”.

3.6.2.5.4 In the first and second sentences, replace “chemicals” and “chemical” with “substances” and “substance” respectively.

3.6.2.5.5 Replace “chemical” with “substance”.

3.6.3.2.1 In the first sentence, insert “both” before “the individual ingredients”.

3.6.3.2.2 In the first sentence:

- amend the beginning to read “If a tested mixture”;
- replace “the new mixture may” with “the new diluted mixture may”; and
- insert “tested” after “original” at the end of the sentence.

3.6.3.2.3 In the first sentence:

- replace “one production batch” with “a tested production batch”;
- delete “complex”;
- replace “another production batch” with “another untested production batch”;
- replace “commercial product produced by and under the control” with “commercial product, when produced by or under the control”; and
- replace “potential of the batch” with “potential of the untested batch”.

3.6.3.2.4 In the last sentence after sub-paragraphs (a) to (d):

- amend the beginning of the sentence to read “If mixture (i) or (ii)”;
- replace “mixture (ii)” with “the other mixture”; and
- insert “hazard” before “category”.

Chapter 3.7

3.7.2.1 At the beginning of the first sentence, delete “chemical”.

3.7.3.2.1 In the first sentence, insert “both” before “the individual ingredients”.

3.7.3.2.2 In the first sentence:

- amend the beginning to read “If a tested mixture”;
- replace “the new mixture may” with “the new diluted mixture may”; and
- insert “tested” after “original” at the end of the sentence.

3.7.3.2.3 In the first sentence:

- replace “one production batch” with “a tested production batch”;
- delete “complex”;
- replace “another production batch” with “another untested production batch”;
- replace “commercial product produced by and under the control” with “commercial product, when produced by or under the control”; and
- replace “potential of the batch” with “potential of the untested batch”.

3.7.3.2.4 In the last sentence after sub-paragraphs (a) to (d):

- amend the beginning of the sentence to read “If mixture (i) or (ii)”;
- replace “mixture (ii)” with “the other mixture”; and
- insert “hazard” before “category”.

Chapter 3.8

3.8.2.1.6 In the last sentence, replace “chemical” with “substance”

3.8.2.1.10.1 In the first sentence replace “chemical” and “chemicals” with “substance” and “substances” respectively.

3.8.2.1.10.2 In the first sentence, delete “chemical” before “substance” and at the beginning of the second sentence, replace “chemical” with “substance”.

3.8.2.1.10.3 Replace “chemical” with “substance”

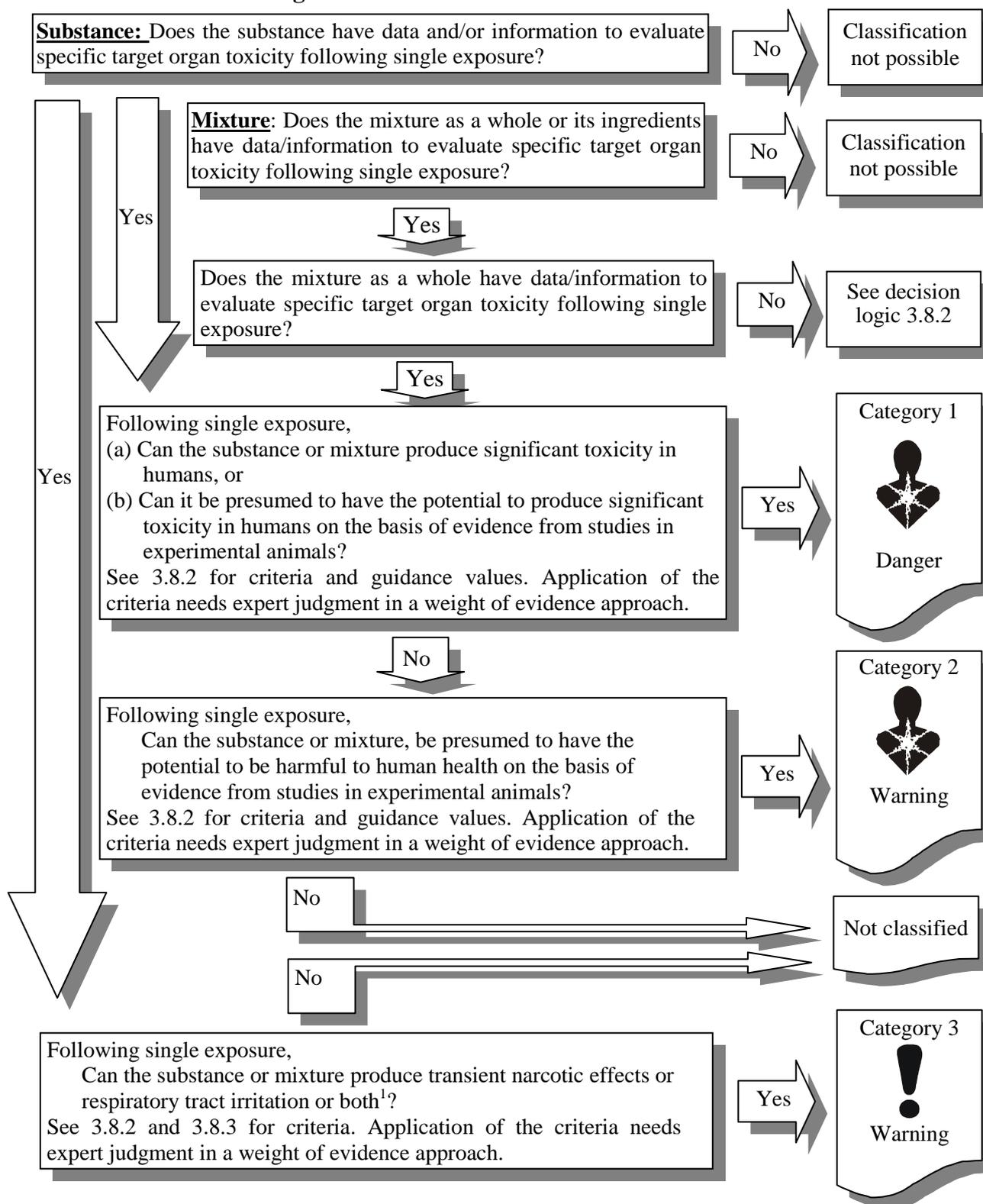
3.8.3.3.1 In the first sentence, insert “both” before “the individual ingredients”.

3.8.3.3.2 In the first sentence:

- amend the beginning to read “If a tested mixture”;
- replace “the new mixture may” with “the new diluted mixture may”; and
- insert “tested” after “original” at the end of the sentence.

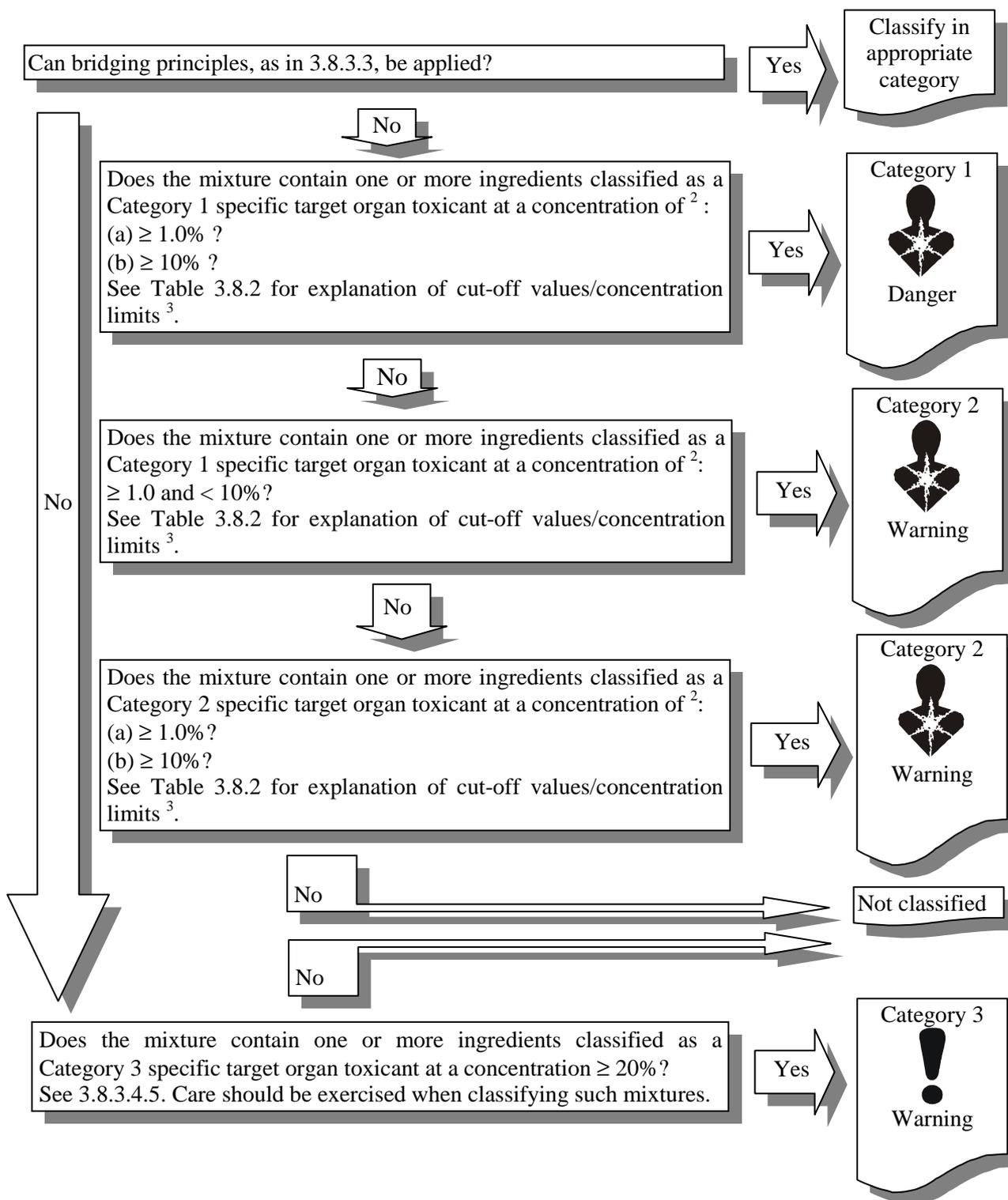
- 3.8.3.3.3 In the first sentence:
- replace “one production batch” with “a tested production batch”;
 - delete “complex”;
 - replace “another production batch” with “another untested production batch”;
 - replace “and produced by” with “when produced by”, and
 - replace “toxicity of the batch” with “toxicity of the untested batch”.
- 3.8.3.3.4 Amend the beginning of the paragraph to read “If in a tested mixture” and insert “resulting” before “concentrated”.
- 3.8.3.3.5 Amend to read as follows:
- “For three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are in the same toxicity category, and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be in the same toxicity category as A and B.”.
- 3.8.3.3.6 In the last sentence after sub-paragraphs (a) to (d):
- amend the beginning of the sentence to read “If mixture (i) or (ii)”;
 - replace “mixture (ii)” with “the other mixture”; and
 - insert “hazard” before “category”.
- 3.8.3.4.5 In the first sentence, replace “extrapolating toxicity” with “extrapolating the toxicity” and add the following sentence at the end of the paragraph:
- “Respiratory tract irritation and narcotic effects are to be evaluated separately in accordance with the criteria given in 3.8.2.2. When conducting classifications for these hazards, the contribution of each ingredient should be considered additive, unless there is evidence that the effects are not additive.”.
- 3.8.5 Amend decision logics 3.8.1 and 3.8.2 in chapter 3.8 to read as follows (current introductory paragraph under 3.8.5 remains unchanged):

“3.8.5.1 Decision logic 3.8.1



¹ Classification in Category 3 would only occur when classification into Category 1 or Category 2 (based on more severe respiratory effects or narcotic effects that are not transient) is not warranted. See 3.8.2.2.1 (e) (respiratory effects) and 3.8.2.2.2 (b) (narcotic effects).

3.8.5.2 Decision logic 3.8.2



² See 3.8.2 of this Chapter and "The use of cut-off values/concentration limits" in Chapter 1.3, para. 1.3.3.2.

³ See 3.8.3.4 and Table 3.8.2 for explanation and guidance.

Chapter 3.9

- 3.9.1.1 At the beginning of the first sentence replace “document” with “chapter” and insert “and mixtures ” after “substances”.
- 3.9.1.2 Replace “chemical substance” with “substance or mixture”.
- 3.9.1.3 In the first sentence, insert “or mixture” after “substance”.
- 3.9.2.6 In the last sentence, replace “chemical” with “substance” (twice).
- 3.9.2.10.1 Replace “chemical” with “substance” (3 times).
- 3.9.2.10.2 In the first sentence delete “chemical” before “substance” and in the second sentence replace “chemical” with “substance”.
- 3.9.2.10.3 Replace “chemical” with “substance”.
- 3.9.3.3.1 In the first sentence, insert “both” before “the individual ingredients”.
- 3.9.3.3.2 In the first sentence:
- amend the beginning to read “If a tested mixture”;
 - replace “the new mixture may” with “the new diluted mixture may”; and
 - insert “tested” after “original” at the end of the sentence.
- 3.9.3.3.3 In the first sentence:
- replace “one production batch” with “a tested production batch”;
 - delete “complex”;
 - replace “another production batch” with “another untested production batch”;
 - replace “and produced by” with “when produced by”, and
 - replace “toxicity of the batch” with “toxicity of the untested batch”
- In the last sentence insert “a” before “new classification”.
- 3.9.3.3.4 Amend the beginning of the paragraph to read “If in a tested mixture” and insert “resulting” before “concentrated”.
- 3.9.3.3.5 Amend to read as follows:
- “For three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are in the same toxicity category, and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be in the same toxicity category as A and B.”.

- 3.9.3.3.6 In the last sentence after the sub-paragraphs:
- amend the beginning of the sentence to read “If mixture (i) or (ii)”;
 - replace “mixture (ii)” with “the other mixture”; and
 - insert “hazard” before “category”.

Chapter 3.10

3.10.1.2 Delete “product”.

3.10.1.6.4 Insert a new paragraph 3.10.1.6.4 to read as follows:

“3.10.1.6.4 Although the definition of aspiration in 3.10.1.2 includes the entry of solids into the respiratory system, classification according to (b) in table 3.10.1 for Category 1 or for Category 2 is intended to apply to liquid substances and mixtures only.”.

Current paragraph 3.10.1.6.4 becomes 3.10.1.6.5.

3.10.3.2.1 In the first sentence, insert “both” before “the individual ingredients”.

3.10.3.2.2 In the first sentence:

- amend the beginning to read “If a tested mixture”;
- replace “the new mixture may” with “the new diluted mixture may”; and
- insert “tested” after “original” at the end of the sentence.

3.10.3.2.3 In the first sentence:

- replace “one production batch” with “a tested production batch”;
- delete “complex”;
- replace “another production batch” with “another untested production batch”;
- replace “and produced by” with “when produced by”, and
- replace “of the batch has changed” with “of the untested batch has changed”

In the last sentence, insert “a” before “new classification”.

3.10.3.2.4 Insert “tested” before “mixture” (twice) at the beginning of the sentence and replace, at the end, “new mixture” with “resulting untested mixture” at the end.

3.10.3.2.5 Amend to read as follows:

“For three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are in the same toxicity category, and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be in the same toxicity category as A and B.”.

3.10.3.2.6 In the sentence after sub-paragraphs (a) to (d):

- amend the beginning of the sentence to read: “If mixture (i) or (ii)”;
- replace “mixture (ii)” with “the other mixture” at the end of the sentence.

PART 4

Chapter 4.1

4.1.1.1 In the definition of “*Acute aquatic toxicity*” insert “aquatic” before “exposure.

In the definition of “*Chronic aquatic toxicity*” replace “potential or actual properties” with “the intrinsic property” and insert “aquatic” before “exposures”.

Insert the following definitions in alphabetical order:

“ EC_x means the concentration associated with $x\%$ response.

Acute (short-term) hazard, for classification purposes, means the hazard of a chemical caused by its acute toxicity to an organism during short-term aquatic exposure to that chemical.

Long-term hazard, for classification purposes, means the hazard of a chemical caused by its chronic toxicity following long-term exposure in the aquatic environment.

NOEC (No Observed Effect Concentration) means the test concentration immediately below the lowest tested concentration with statistically significant adverse effect. The NOEC has no statistically significant adverse effect compared to the control.”

4.1.1.2.1 Rearrange current sub-paragraphs (a) to (d) to read as follows:

- “(a) acute aquatic toxicity;
- (b) chronic aquatic toxicity;
- (c) potential for or actual bioaccumulation; and
- (d) degradation (biotic or abiotic) for organic chemicals.”.

4.1.1.4 (former 4.1.1.6) Current paragraph 4.1.1.6 becomes new paragraph 4.1.1.4 with the following modification:

In the last sentence replace “L(E)Cx” with “ EC_x ”.

4.1.1.5 (former 4.1.1.4) Current paragraph 4.1.1.4 becomes new paragraph 4.1.1.5.

4.1.1.6, 4.1.1.6.1 and 4.1.1.6.2 (former 4.1.1.5, 4.1.1.5.1 and 4.1.1.5.2):

Current paragraphs 4.1.1.5, 4.1.1.5.1 and 4.1.1.5.2 become new paragraphs 4.1.1.6, 4.1.1.6.1 and 4.1.1.6.2, respectively.

In new paragraph 4.1.1.6.1, replace “(See 4.1.2.10.3)” with “(see 4.1.2.11.3).

4.1.1.7.1 At the first sentence, delete “chemical” before “substances” and replace “4.1.1.7.4” with “4.1.1.7.3”.

4.1.1.7.2 and 4.1.1.7.3 Delete the last sentence of current paragraphs 4.1.1.7.2 (“For instance... No.29”) and 4.1.1.7.3 (“(As noted above, Annex 10 is subject to validation)”) and merge both paragraphs into one unique paragraph 4.1.1.7.2.

As a consequence, current paragraph 4.1.1.7.4 becomes new paragraph 4.1.1.7.3.

4.1.2.1 Amend to read as follows:

“4.1.2.1 Whilst the harmonized classification system consists of three acute classification categories and four chronic classification categories, the core part of the harmonized classification system for substances consists of three acute classification categories and three chronic classification categories (see Table 4.1.1 (a) and (b)). The acute and the chronic classification categories are applied independently. The criteria for classification of a substance in categories Acute 1 to 3 are defined on the basis of the acute toxicity data only (EC₅₀ or LC₅₀). The criteria for classification of a substance into categories Chronic 1 to 3 follow a tiered approach where the first step is to see if available information on chronic toxicity merits long-term hazard classification. In absence of adequate chronic toxicity data, the subsequent step is to combine two types of information, i.e. acute toxicity data and environmental fate data (degradability and bioaccumulation data) (see Figure 4.1.1).”

4.1.2.2 (former 4.1.2.12) Current paragraph 4.1.2.12 becomes new paragraph 4.1.2.2, with the following modifications:

- Delete the title (“Category Chronic 4”);
- In the third sentence, replace “poorly water soluble organic substances” with “poorly water soluble substances”;
- Amend the last sentence to read as follows:

“The need for this classification can be negated by demonstrating that the substance does not require classification for aquatic long-term hazards.”.

4.1.2.3 (new) Insert a new paragraph to read as follows:

“4.1.2.3 Substances with acute toxicities well below 1 mg/l or chronic toxicities well below 0.1 mg/l (if non-rapidly degradable) and 0.01 mg/l (if rapidly

degradable) contribute as ingredients of a mixture to the toxicity of the mixture even at a low concentration and should be given increased weight in applying the summation method (see Note 2 to Table 4.1.1 and paragraph 4.1.3.5.5.5).”

Current paragraph 4.1.2.3 becomes new paragraph 4.1.2.5.

4.1.2.4 (former 4.1.2.2) Current paragraph 4.1.2.2 becomes new paragraph 4.1.2.4, with the following modifications:

- In the first sentence insert “(Table 4.1.1)” after “following criteria”; and
- in the last sentence replace “Table 4.1.1” with “Table 4.1.2”.

Figure 4.1.1 and Table 4.1.1: Replace with the following new table 4.1.1:

Table 4.1.1: Categories for substances hazardous to the aquatic environment (Note 1)

(a) Acute (short-term) aquatic hazard	
Category Acute 1: (Note 2)	
96 hr LC ₅₀ (for fish)	≤ 1 mg/l and/or
48 hr EC ₅₀ (for crustacea)	≤ 1 mg/l and/or
72 or 96hr ErC ₅₀ (for algae or other aquatic plants)	≤ 1 mg/l (Note 3)
Category Acute 1 may be subdivided for some regulatory systems to include a lower band at L(E)C ₅₀ ≤ 0.1 mg/l.	
Category Acute 2:	
96 hr LC ₅₀ (for fish)	> 1 but ≤ 10 mg/l and/or
48 hr EC ₅₀ (for crustacea)	>1 but ≤ 10 mg/l and/or
72 or 96hr ErC ₅₀ (for algae or other aquatic plants)	>1 but ≤ 10 mg/l (Note 3)
Category Acute 3:	
96 hr LC ₅₀ (for fish)	>10 but ≤ 100 mg/l and/or
48 hr EC ₅₀ (for crustacea)	>10 but ≤ 100 mg/l and/or
72 or 96hr ErC ₅₀ (for algae or other aquatic plants)	>10 but ≤ 100 mg/l (Note 3)
Some regulatory systems may extend this range beyond an L(E)C ₅₀ of 100 mg/l through the introduction of another category.	
(b) Long-term aquatic hazard (see also figure 4.1.1)	
(i) Non-rapidly degradable substances (Note 4) for which there are adequate chronic toxicity data available	
Category Chronic 1: (Note 2)	
Chronic NOEC or EC _x (for fish)	≤ 0.1 mg/l and/or
Chronic NOEC or EC _x (for crustacea)	≤ 0.1 mg/l and/or
Chronic NOEC or EC _x (for algae or other aquatic plants)	≤ 0.1 mg/l
Category Chronic 2:	
Chronic NOEC or EC _x (for fish)	≤ 1 mg/l and/or
Chronic NOEC or EC _x (for crustacea)	≤ 1 mg/l and/or
Chronic NOEC or EC _x (for algae or other aquatic plants)	≤ 1 mg/l

(Cont'd on next page)

Table 4.1.1: Categories for substances hazardous to the aquatic environment (Note 1) (cont'd)

(ii) Rapidly degradable substances for which there are adequate chronic toxicity data available	
<u>Category Chronic 1:</u> (Note 2)	
Chronic NOEC or EC _x (for fish)	≤ 0.01 mg/l and/or
Chronic NOEC or EC _x (for crustacea)	≤ 0.01 mg/l and/or
Chronic NOEC or EC _x (for algae or other aquatic plants)	≤ 0.01 mg/l
<u>Category Chronic 2:</u>	
Chronic NOEC or EC _x (for fish)	≤ 0.1 mg/l and/or
Chronic NOEC or EC _x (for crustacea)	≤ 0.1 mg/l and/or
Chronic NOEC or EC _x (for algae or other aquatic plants)	≤ 0.1 mg/l
<u>Category Chronic 3:</u>	
Chronic NOEC or EC _x (for fish)	≤ 1 mg/l and/or
Chronic NOEC or EC _x (for crustacea)	≤ 1 mg/l and/or
Chronic NOEC or EC _x (for algae or other aquatic plants)	≤ 1 mg/l
(iii) Substances for which adequate chronic toxicity data are not available	
<u>Category Chronic 1:</u> (Note 2)	
96 hr LC ₅₀ (for fish)	≤ 1 mg/l and/or
48 hr EC ₅₀ (for crustacea)	≤ 1 mg/l and/or
72 or 96hr ErC ₅₀ (for algae or other aquatic plants)	≤ 1 mg/l (Note 3)
and the substance is not rapidly degradable and/or the experimentally determined BCF is ≥ 500 (or, if absent, the log K _{ow} ≥ 4). (Notes 4 and 5)	
<u>Category Chronic 2:</u>	
96 hr LC ₅₀ (for fish)	> 1 but ≤ 10 mg/l and/or
48 hr EC ₅₀ (for crustacea)	> 1 but ≤ 10 mg/l and/or
72 or 96hr ErC ₅₀ (for algae or other aquatic plants)	> 1 but ≤ 10 mg/l (Note 3)
and the substance is not rapidly degradable and/or the experimentally determined BCF is ≥ 500 (or, if absent, the log K _{ow} ≥ 4). (Notes 4 and 5)	
<u>Category Chronic 3:</u>	
96 hr LC ₅₀ (for fish)	> 10 but ≤ 100 mg/l and/or
48 hr EC ₅₀ (for crustacea)	> 10 but ≤ 100 mg/l and/or
72 or 96hr ErC ₅₀ (for algae or other aquatic plants)	> 10 but ≤ 100 mg/l (Note 3)
and the substance is not rapidly degradable and/or the experimentally determined BCF is ≥ 500 (or, if absent, the log K _{ow} ≥ 4). (Notes 4 and 5).	
(c) "Safety net" classification	
<u>Category Chronic 4:</u>	
Poorly soluble substances for which no acute toxicity is recorded at levels up to the water solubility, and which are not rapidly degradable and have a log K _{ow} ≥ 4, indicating a potential to bioaccumulate, will be classified in this category unless other scientific evidence exists showing classification to be unnecessary. Such evidence would include an experimentally determined BCF < 500, or a chronic toxicity NOECs > 1 mg/l, or evidence of rapid degradation in the environment.	

Amend Notes 1 to 5 to table 4.1.1 to read as follows:

NOTE 1: *The organisms fish, crustacea and algae are tested as surrogate species covering a range of trophic levels and taxa, and the test methods are highly standardized. Data on other organisms may also be considered, however, provided they represent equivalent species and test endpoints.*

NOTE 2: *When classifying substances as Acute 1 and/or Chronic 1 it is necessary at the same time to indicate an appropriate M factor (see 4.1.3.5.5.5) to apply the summation method.*

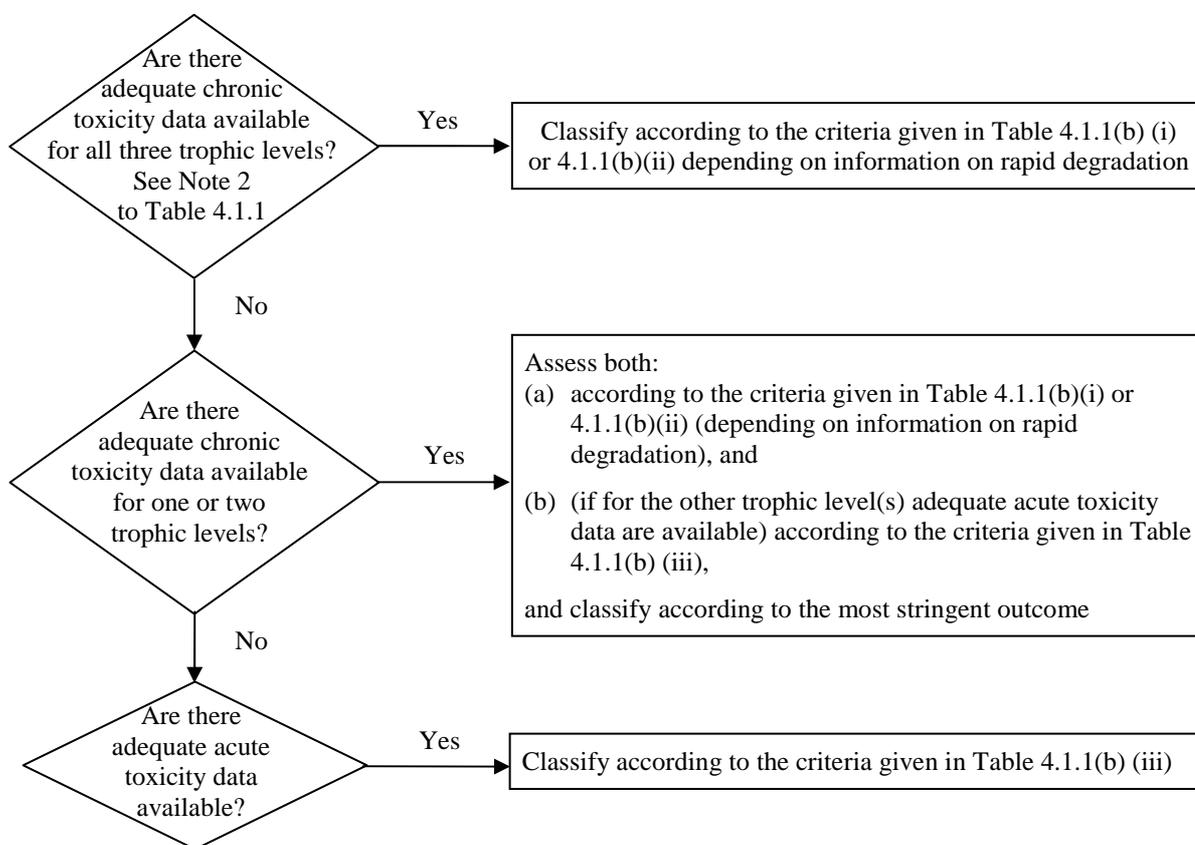
NOTE 3: *Where the algal toxicity ErC_{50} [= EC_{50} (growth rate)] falls more than 100 times below the next most sensitive species and results in a classification based solely on this effect, consideration should be given to whether this toxicity is representative of the toxicity to aquatic plants. Where it can be shown that this is not the case, professional judgment should be used in deciding if classification should be applied. Classification should be based on the ErC_{50} . In circumstances where the basis of the EC_{50} is not specified and no ErC_{50} is recorded, classification should be based on the lowest EC_{50} available.*

NOTE 4: *Lack of rapid degradability is based on either a lack of ready biodegradability or other evidence of lack of rapid degradation. When no useful data on degradability are available, either experimentally determined or estimated data, the substance should be regarded as not rapidly degradable.*

NOTE 5: *Potential to bioaccumulate based on an experimentally derived $BCF \geq 500$ or, if absent, a $\log K_{ow} \geq 4$ provided $\log K_{ow}$ is an appropriate descriptor for the bioaccumulation potential of the substance. Measured $\log K_{ow}$ values take precedence over estimated values and measured BCF values take precedence over $\log K_{ow}$ values.”.*

Figure 4.1.1: Insert a new figure 4.1.1 to read as follows:

“Figure 4.1.1: Categories for substances long-term hazardous to the aquatic environment



”

4.1.2.5 (former 4.1.2.3) Current paragraph 4.1.2.3 becomes new paragraph 4.1.2.5 with the following modifications:

- In the second sentence, replace “chronic hazard” with “long-term hazard”.
- Amend the third sentence to read as follows:

“The lowest of the available toxicity values between and within the different trophic levels (fish, crustacean, algae) will normally be used to define the appropriate hazard category(ies).”

- Delete the last sentence (“For that reason...system”).

4.1.2.6 (former 4.1.2.4) Current paragraph 4.1.2.4 becomes new paragraph 4.1.2.6.

4.1.2.7 (former 4.1.2.5) Current paragraph 4.1.2.5 becomes new paragraph 4.1.2.7 with the following modifications:

- In the third sentence, replace “short-term toxicity” with “acute toxicity”.
- In the fifth sentence, insert “in those cases” before “it is necessary”.

- In the sixth sentence, replace “chronic” with “long-term”.
- Amend the seventh sentence to read as follows:

“Where chronic toxicity is available showing NOECs greater than water solubility or greater than 1 mg/l, this would indicate that no classification in any of the long-term hazard categories Chronic 1 to 3 would be necessary.”.

4.1.2.6 Delete.

4.1.2.8 (former 4.1.2.7) Current paragraph 4.1.2.7 becomes new paragraph 4.1.2.8.

4.1.2.9, 4.1.2.9.1 and 4.1.2.9.2 (former 4.1.2.8, 4.1.2.8.1 and 4.1.2.8.2):

Current paragraphs 4.1.2.8, 4.1.2.8.1 and 4.1.2.8.2, become new paragraphs 4.1.2.9, 4.1.2.9.1 and 4.1.2.9.2, respectively.

4.1.2.10 (former 4.1.2.9) Current paragraph 4.1.2.9 becomes new paragraph 4.1.2.10, with the following modification:

Add the following sentence at the end of the current text:

“Some relationships can be observed between chronic toxicity and bioaccumulation potential, as toxicity is related to the body burden.”.

4.1.2.11, 4.1.2.11.1, 4.1.2.11.2, 4.1.2.11.3, 4.1.2.12, 4.1.2.12.1 and 4.1.2.12.2 (former 4.1.2.10, 4.1.2.10.1, 4.1.2.10.2, 4.1.2.10.3, 4.1.2.11, 4.1.2.11.1 and 4.1.2.11.2).

Current paragraphs 4.1.2.10, 4.1.2.10.1, 4.1.2.10.2, 4.1.2.10.3, 4.1.2.11, 4.1.2.11.1 and 4.1.2.11.2 become new paragraphs 4.1.2.11, 4.1.2.11.1, 4.1.2.11.2, 4.1.2.11.3, 4.1.2.12, 4.1.2.12.1 and 4.1.2.12.2, respectively.

4.1.2.11.3 (a) (former 4.1.2.11.3 (a)) Amend the paragraph after (ii) to read as follows:

“These levels of biodegradation must be achieved within 10 days of the start of degradation which point is taken as the time when 10% of the substance has been degraded, unless the substance is identified as a complex, multi-component substance with structurally similar constituents. In this case, and where there is sufficient justification, the 10-day window condition may be waived and the pass level applied at 28 days as explained in Annex 9 (A9.4.2.2.3)”.

4.1.2.12.2 (former 4.1.2.11.2) Replace the last sentence with the following text:

“All evidence must be weighed in a classification decision. This would be especially true for metals showing borderline results in the Transformation/Dissolution Protocol.”.

4.1.2.14 Insert a new sub-section 4.1.2.14 to read as follows:

“4.1.2.14 The classification criteria for substances diagrammatically summarized

Table 4.1.2: Classification scheme for substances hazardous to the aquatic environment

Classification categories			
Acute hazard (Note 1)	Long-term hazard (Note 2)		
	Adequate chronic toxicity data available		Adequate chronic toxicity data not available (Note 1)
	Non-rapidly degradable substances (Note 3)	Rapidly degradable substances (Note 3)	
Category: Acute 1	Category: Chronic 1	Category: Chronic 1	Category: Chronic 1
$L(E)C_{50} \leq 1.00$	$NOEC \text{ or } EC_x \leq 0.1$	$NOEC \text{ or } EC_x \leq 0.01$	$L(E)C_{50} \leq 1.00$ and lack of rapid degradability and/or $BCF \geq 500$ or, if absent $\log K_{ow} \geq 4$
Category: Acute 2	Category: Chronic 2	Category: Chronic 2	Category: Chronic 2
$1.00 < L(E)C_{50} \leq 10.0$	$0.1 < NOEC \text{ or } EC_x \leq 1$	$0.01 < NOEC \text{ or } EC_x \leq 0.1$	$1.00 < L(E)C_{50} \leq 10.0$ and lack of rapid degradability and/or $BCF \geq 500$ or, if absent $\log K_{ow} \geq 4$
Category: Acute 3		Category: Chronic 3	Category: Chronic 3
$10.0 < L(E)C_{50} \leq 100$		$0.1 < NOEC \text{ or } EC_x \leq 1$	$10.0 < L(E)C_{50} \leq 100$ and lack of rapid degradability and/or $BCF \geq 500$ or, if absent $\log K_{ow} \geq 4$
	Category: Chronic 4 (Note 4) Example: (Note 5) No acute toxicity and lack of rapid degradability and $BCF \geq 500$ or, if absent $\log K_{ow} \geq 4$, unless $NOECs > 1 \text{ mg/l}$		

NOTE 1: Acute toxicity band based on $L(E)C_{50}$ values in mg/l for fish, crustacea and/or algae or other aquatic plants (or QSAR estimation if no experimental data).

NOTE 2: Substances are classified in the various chronic categories unless there are adequate chronic toxicity data available for all three trophic levels above the water solubility or above 1 mg/l. (“Adequate” means that the data sufficiently cover the endpoint of concern. Generally this would mean measured test data, but in order to avoid unnecessary testing it can, on a case-by-case basis, also be estimated data, e.g. (Q)SAR, or for obvious cases expert judgment).

NOTE 3: Chronic toxicity band based on $NOEC$ or equivalent EC_x values in mg/l for fish or crustacea or other recognized measures for chronic toxicity.

NOTE 4: The system also introduces a “safety net” classification (referred to as category Chronic 4) for use when the data available do not allow classification under the formal criteria but there are nevertheless some grounds for concern.

NOTE 5: *For poorly soluble substances for which no acute toxicity has been demonstrated at the solubility limit, and are both not rapidly degraded and have a potential to bioaccumulate, this category should apply unless it can be demonstrated that the substance does not require classification for aquatic long-term hazards.”.*

4.1.3.1 Amend the second paragraph to read as follows:

“The “relevant ingredients” of a mixture are those which are present in a concentration equal to or greater than 0.1% (w/w) for ingredients classified as Acute and/or Chronic 1 and equal to or greater than 1% (w/w) for other ingredients, unless there is a presumption (e.g. in the case of highly toxic ingredients) that an ingredient present at a concentration less than 0.1% can still be relevant for classifying the mixture for aquatic environmental hazards.”.

Figure 4.1.2 In the title, replace “chronic” with “long-term”;

After “CLASSIFY” on the right hand side, replace (4 times) “chronic toxicity hazard” with “long-term hazard”.

Amend (c) to read as follows:

“Percentage of ingredients with acute toxicity data: apply additivity formulas (see 4.1.3.5.2) and convert the derived L(E)C₅₀ or EqNOEC_m to the appropriate “Acute” or “Chronic” category”.

4.1.3.3 Amend to read as follows:

”4.1.3.3 Classification of mixtures when toxicity data are available for the complete mixture

4.1.3.3.1 When the mixture as a whole has been tested to determine its aquatic toxicity, this information can be used for classifying the mixture according to the criteria that have been agreed for substances. The classification should normally be based on the data for fish, crustacea and algae/plants (see 4.1.1.3 and 4.1.1.4). When adequate acute or chronic data for the mixture as a whole are lacking, “bridging principles” or “summation method” should be applied (see paragraphs 4.1.3.4 and 4.1.3.5 and decision logic 4.1.5.2.2).

4.1.3.3.2 The long-term hazard classification of mixtures requires additional information on degradability and in certain cases bioaccumulation. There are no degradability and bioaccumulation data for mixtures as a whole. Degradability and bioaccumulation tests for mixtures are not used as they are usually difficult to interpret, and such tests may be meaningful only for single substances.

4.1.3.3.3 *Classification for categories Acute 1, 2 and 3*

- (a) When there are adequate acute toxicity test data (LC₅₀ or EC₅₀) available for the mixture as a whole showing L(E)C₅₀ ≤ 100 mg/l:

Classify the mixture as Acute 1, 2 or 3 in accordance with Table 4.1.1(a)

- (b) When there are acute toxicity test data (LC₅₀(s) or EC₅₀(s)) available for the mixture as a whole showing L(E)C₅₀(s) >100 mg/l, or above the water solubility:

No need to classify for acute hazard

4.1.3.3.4 *Classification for categories Chronic 1, 2 and 3*

- (a) When there are adequate chronic toxicity data (EC_x or NOEC) available for the mixture as a whole showing EC_x or NOEC of the tested mixture ≤ 1 mg/l:

(i) Classify the mixture as Chronic 1, 2 or 3 in accordance with Table 4.1.1 (b)(ii) (rapidly degradable) if the available information allows the conclusion that all relevant ingredients of the mixture are rapidly degradable;

(ii) Classify the mixture as Chronic 1, 2 or 3 in all other cases in accordance with Table 4.1.1 (b)(i) (non-rapidly degradable);

- (b) When there are adequate chronic toxicity data (EC_x or NOEC) available for the mixture as a whole showing EC_x(s) or NOEC(s) of the tested mixture > 1mg/l or above the water solubility:

No need to classify for long-term hazard, unless there are nevertheless reasons for concern

4.1.3.3.5 *Classification for category Chronic 4*

If there are nevertheless reasons for concern:

Classify the mixture as Chronic 4 (safety net classification) in accordance with Table 4.1.1 (c)".

4.1.3.4 In the title, insert "toxicity" before "data".

4.1.3.4.2 In the first paragraph:

- amend the beginning to read “Where a new mixture is formed by diluting a tested mixture or”;
- replace “the mixture may” with “the resulting mixture may”;
- insert “tested” after “original”; and
- add the following new sentence at the end of the paragraph: “Alternatively, the method explained in 4.1.3.5 could be applied”.

Delete the second paragraph.

4.1.3.4.3 In the first sentence:

- replace “one production batch” with “a tested production batch”;
- delete “complex”;
- replace “another production batch” with “another untested production batch”;
- replace “and produced by” with “when produced by”, and
- insert “untested” before “batch” at the end.

4.1.3.4.4 Amend the beginning to read: “If a tested mixture”;

Insert “the” before “ingredients”;

Replace “more concentrated mixture” with “more concentrated untested mixture”;
and

Insert “tested” after “original”.

4.1.3.4.5 Amend to read as follows:

“For three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are in the same toxicity category, and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be in the same toxicity category as A and B.”.

4.1.3.4.6 In sub-paragraph (b), insert “essentially” before “the same”.

In sub-paragraph (d), replace “Classification” with “Data on aquatic hazards” and replace “are the same” with “are substantially equivalent”.

Amend the last sentence after the sub-paragraphs to read as follows:

“If mixture (i) or (ii) is already classified based on test data, then the other mixture can be assigned the same hazard category.”.

4.1.3.5 In the title, insert “toxicity” before “data”.

4.1.3.5.2 Amend to read as follows:

“4.1.3.5.2 Mixtures can be made of a combination of both ingredients that are classified (as Acute 1, 2, 3 and/or Chronic 1, 2, 3, 4) and those for which adequate toxicity test data are available. When adequate toxicity data are available for more than one ingredient in the mixture, the combined toxicity of those ingredients may be calculated using the following additivity formulas (a) or (b), depending on the nature of the toxicity data:

(a) Based on acute aquatic toxicity:

$$\frac{\sum C_i}{L(E)C_{50_m}} = \sum_n \frac{C_i}{L(E)C_{50_i}}$$

where:

- C_i = concentration of ingredient i (weight percentage);
- $L(E)C_{50_i}$ = LC_{50} or EC_{50} for ingredient i, in mg/l;
- n = number of ingredients, and i is running from 1 to n;
- $L(E)C_{50_m}$ = $L(E)C_{50}$ of the part of the mixture with test data;

The calculated toxicity may be used to assign that portion of the mixture an acute hazard category which is then subsequently used in applying the summation method;

(b) Based on chronic aquatic toxicity:

$$\frac{\sum C_i + \sum C_j}{EqNOEC_m} = \sum_n \frac{C_i}{NOEC_i} + \sum_n \frac{C_j}{0.1 \times NOEC_j}$$

where:

- C_i = concentration of ingredient i (weight percentage) covering the rapidly degradable ingredients;
- C_j = concentration of ingredient j (weight percentage) covering the non-rapidly degradable ingredients;
- $NOEC_i$ = NOEC (or other recognized measures for chronic toxicity) for ingredient i covering the rapidly degradable ingredients, in mg/l;
- $NOEC_j$ = NOEC (or other recognized measures for chronic toxicity) for ingredient j covering the non-rapidly degradable ingredients, in mg/l;
- n = number of ingredients, and i and j are running from 1 to n;
- $EqNOEC_m$ = Equivalent NOEC of the part of the mixture with test data;

The equivalent toxicity thus reflects the fact that non-rapidly degrading substances are classified one hazard category level more “severe” than rapidly degrading substances.

The calculated equivalent toxicity may be used to assign that portion of the mixture a long-term hazard category, in accordance with the criteria for rapidly degradable substances (Table 4.1.1 (b)(ii)), which is then subsequently used in applying the summation method.”.

- 4.1.3.5.3 In the first sentence, replace “to the same species (i.e. fish, daphnia or algae)” with “to the same taxonomic group (i.e. fish, crustacean or algae)” and “of the three species” with “of the three groups”.

In the second sentence, replace “same species” with “same taxonomic group”.

In the last sentence, replace “The calculated acute toxicity” with “The calculated acute and chronic toxicity” and insert “and/or Chronic 1, 2 or 3” after “Acute 1, 2 or 3”.

- 4.1.3.5.5.1.2 Amend the first sentence to read as follows:

“When a mixture contains ingredients classified as Acute 1 or Chronic 1, attention should be paid to the fact that such ingredients, when their acute toxicity is well below 1 mg/l and/or chronic toxicity is well below 0.1 mg/l (if non-rapidly degradable) and 0.01 mg/l (if rapidly degradable) contribute to the toxicity of the mixture even at a low concentration (see also *Classification of hazardous substances and mixtures* in Chapter 1.3, paragraph 1.3.3.2.1).”

- 4.1.3.5.5.3.1, 4.1.3.5.5.3.2, 4.1.3.5.5.3.3, 4.1.3.5.5.4.2,
4.1.3.5.5.4.3, 4.1.3.5.5.4.4 and decision logic 4.1.1:

Replace “sum of... ingredients” by “sum of the concentrations (in %) of...ingredients”.

- 4.1.3.5.5.3.4 Replace “summation of classified ingredients” with “summation of the concentrations of the classified ingredients” and “Table 4.1.2” with “Table 4.1.3”.

Table 4.1.2 Renumber as “Table 4.1.3” and replace “summation of classified ingredients” with “summation of the concentrations of classified ingredients”

- 4.1.3.5.5.4.1 At the beginning of the second sentence replace “If the sum of these ingredients” with “If the sum of the concentrations (in %) of these ingredients”.

- 4.1.3.5.5.4.5 Replace “chronic” with “long-term”, “summation of classified ingredients” with “summation of the concentrations of classified ingredients” and “Table 4.1.3” with “Table 4.1.4”.

Table 4.1.3 Renumber as “Table 4.1.4” and replace, in the title, “chronic” with “long-term” and insert “the concentrations of” before “classified ingredients”.

4.1.3.5.5.5 Amend the first sentence to read as follows:

“Acute 1 or Chronic 1 ingredients with acute toxicities well below 1 mg/l and/or chronic toxicities well below 0.1 mg/l (if non-rapidly degradable) and 0.01 mg/l (if rapidly degradable) may influence the toxicity of the mixture and should be given increased weight in applying the summation method.”

In the second sentence replace “concentrations of Acute 1 ingredients” with “concentrations of Acute 1 and Chronic 1 ingredients”

In the third sentence, replace “Table 4.1.2” and “Table 4.1.3” with “Table 4.1.3” and “Table 4.1.4” respectively.

In the fourth sentence, replace “Table 4.1.4” with “Table 4.1.5”

In the last sentence, replace “specific acute toxicity data” with “specific acute and/or chronic toxicity data”.

Table 4.1.4 Renumber as “Table 4.1.5” and amend to read as follows:

“Table 4.1.5: Multiplying factors for highly toxic ingredients of mixtures

Acute toxicity L(E)C ₅₀ value	M factor	Chronic toxicity NOEC value	M factor	
			NRD ^a ingredients	RD ^b ingredients
0.1 < L(E)C ₅₀ ≤ 1	1	0.01 < NOEC ≤ 0.1	1	-
0.01 < L(E)C ₅₀ ≤ 0.1	10	0.001 < NOEC ≤ 0.01	10	1
0.001 < L(E)C ₅₀ ≤ 0.01	100	0.0001 < NOEC ≤ 0.001	100	10
0.0001 < L(E)C ₅₀ ≤ 0.001	1000	0.00001 < NOEC ≤ 0.0001	1000	100
0.00001 < L(E)C ₅₀ ≤ 0.0001	10000	0.000001 < NOEC ≤ 0.00001	10000	1000
(continue in factor 10 intervals)		(continue in factor 10 intervals)		

^a Non-rapidly degradable

^b Rapidly degradable

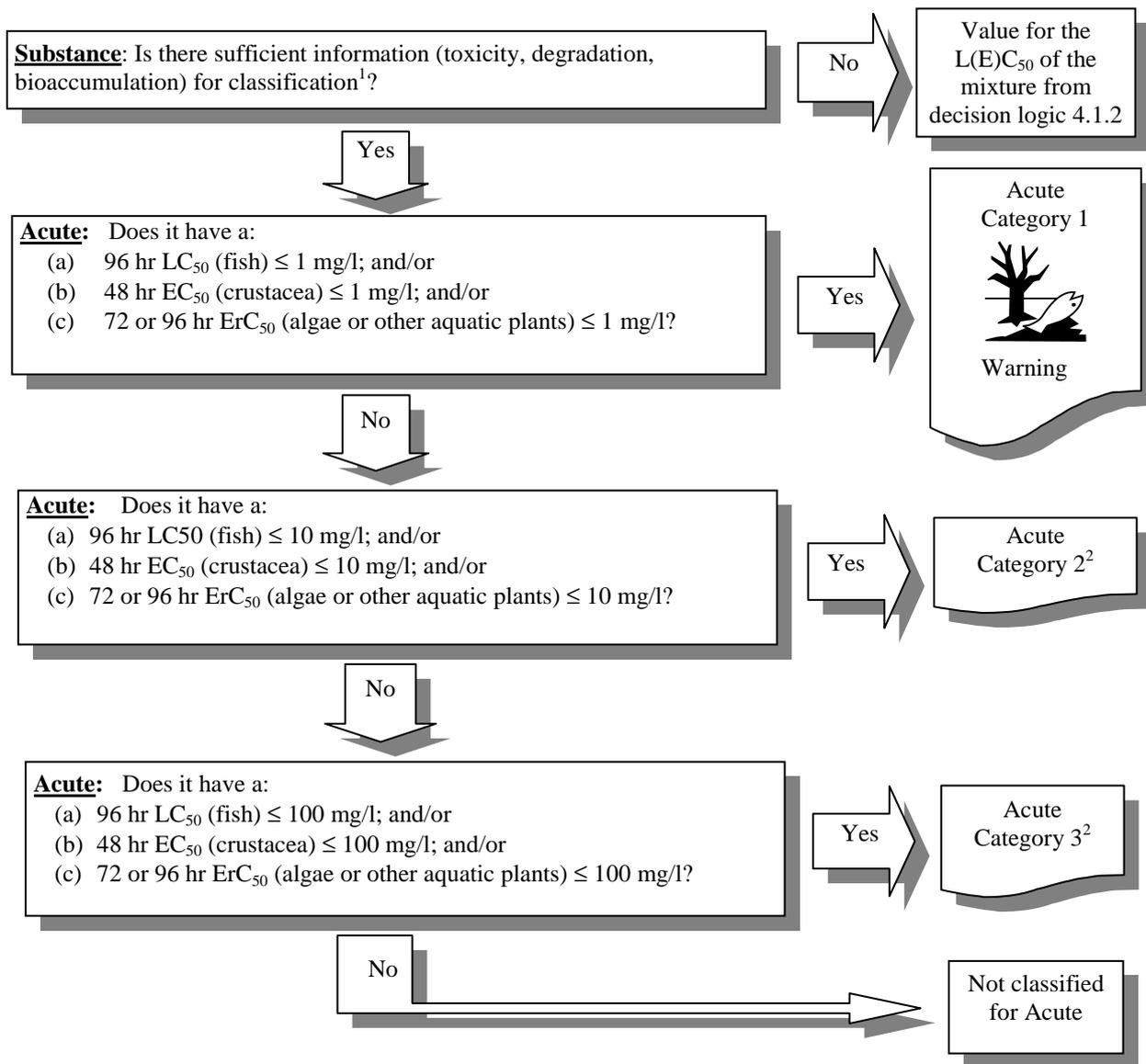
4.1.3.6 In the first sentence, replace “chronic aquatic hazard” with “chronic aquatic toxicity”.

Table 4.1.5 Renumber as “Table 4.1.6”

4.1.5.1 Replace current decision logics with the following:

“4.1.5.1 Acute (short-term) aquatic hazard classification

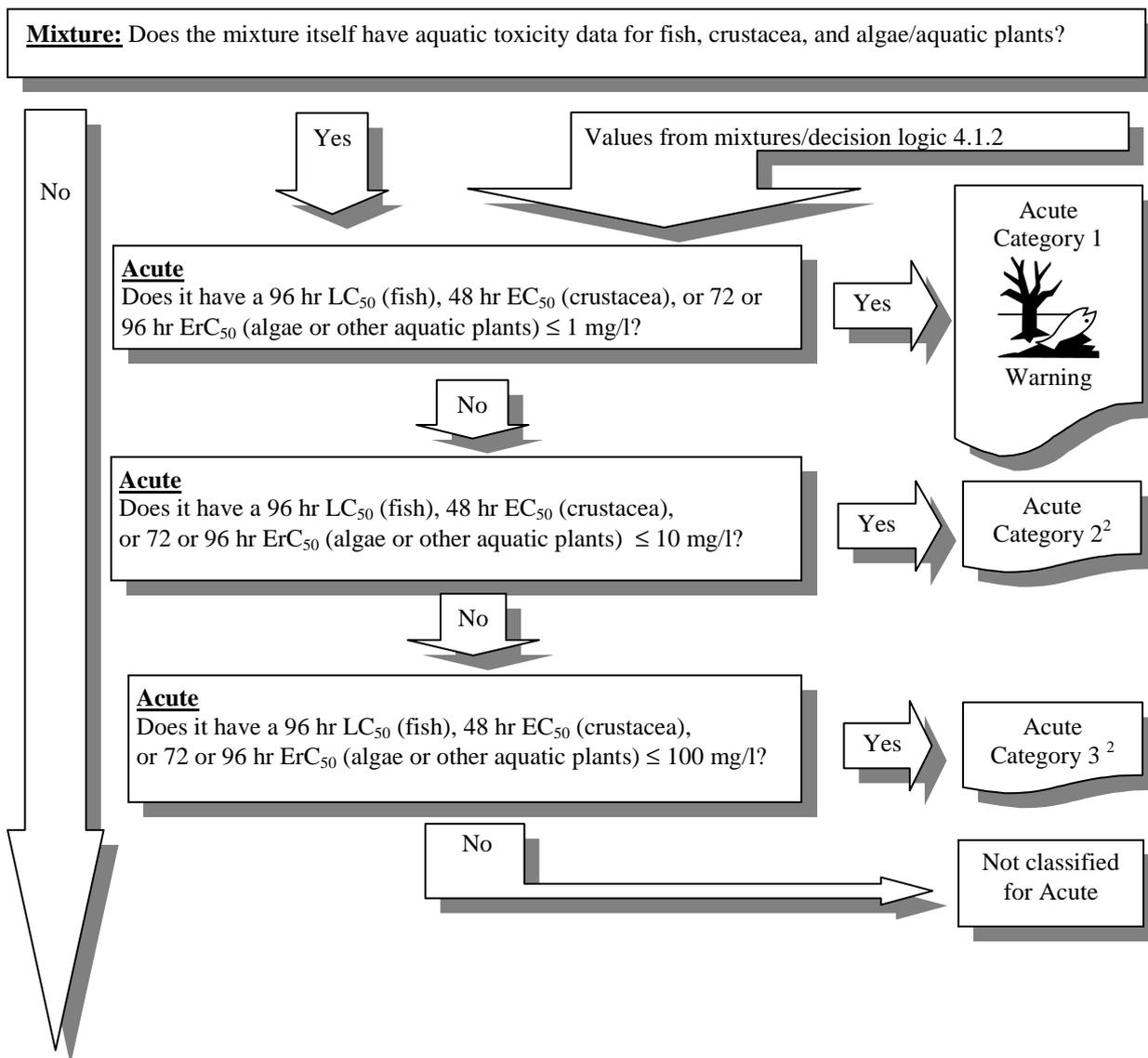
4.1.5.1.1 Decision logic 4.1.1 for substances and mixtures hazardous to the aquatic environment



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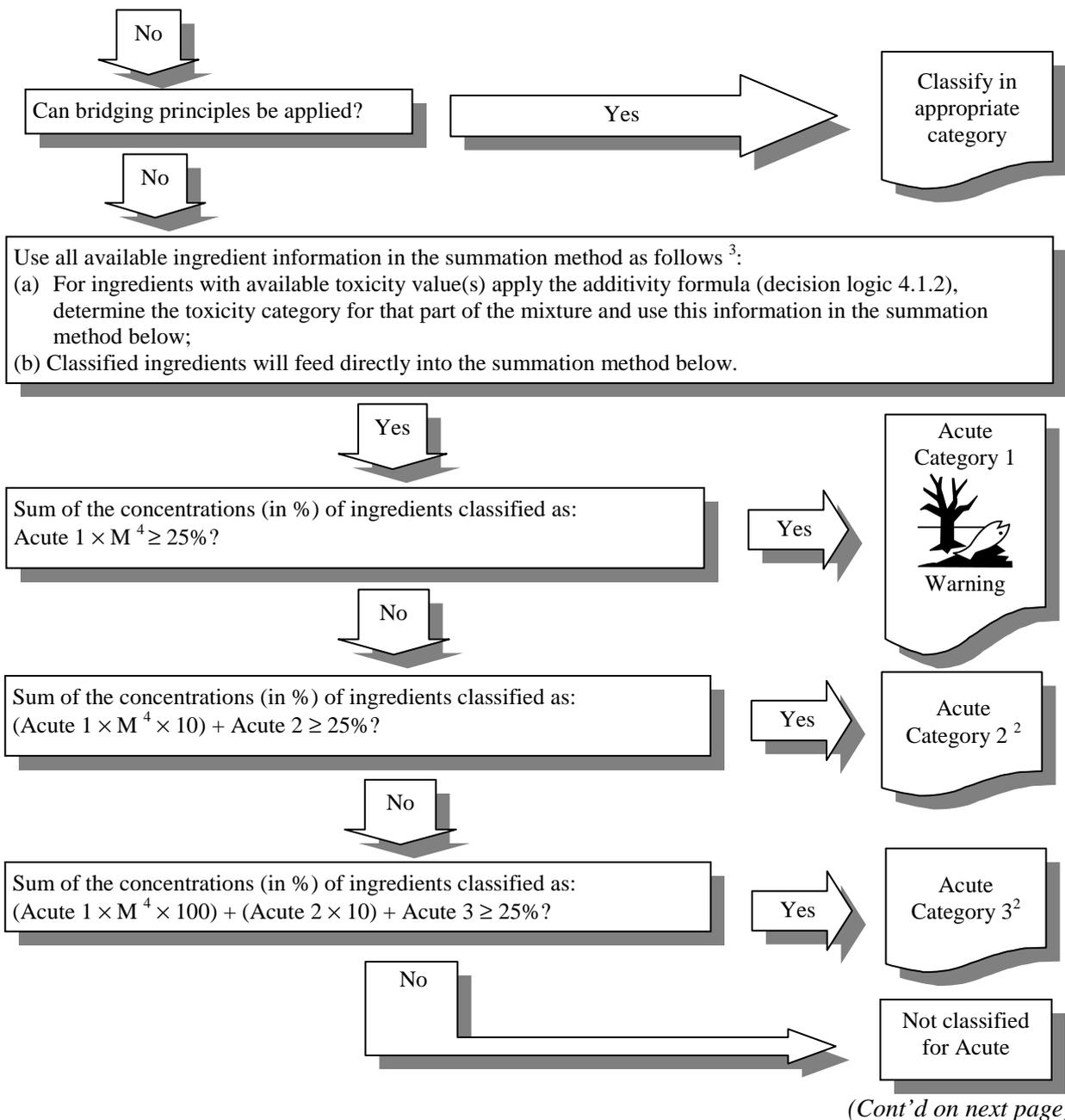
¹ Classification can be based on either measured data and/or calculated data (see 4.1.2.13 and Annex 9) and/or analogy decisions (see A9.6.4.5 in Annex 9).

² Labelling requirements differ from one regulatory system to another, and certain classification categories may only be used in one or a few regulations.



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² Labelling requirements differ from one regulatory system to another, and certain classification categories may only be used in one or a few regulations.



² Labelling requirements differ from one regulatory system to another, and certain classification categories may only be used in one or a few regulations.

³ If not all ingredients have information, include the statement "x % of the mixture consists of ingredient(s) of unknown hazards to the aquatic environment" on the label. Alternatively, in the case of a mixture with highly toxic ingredients, if toxicity values are available for these highly toxic ingredients and all other ingredients do not significantly contribute to the hazard of the mixture, then the additivity formula may be applied (see 4.1.3.5.5.5). In this case and other cases where toxicity values are available for all ingredients, the acute classification may be made solely on the basis of the additivity formula.

⁴ For explanation of M factor see 4.1.3.5.5.5.

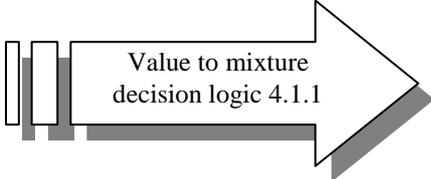
4.1.5.1.2 Decision logic 4.1.2 for mixtures (additivity formula)

Apply the additivity formula:

$$\frac{\sum C_i}{L(E)C_{50_m}} = \sum \frac{C_i}{L(E)C_{50_i}}$$

where:

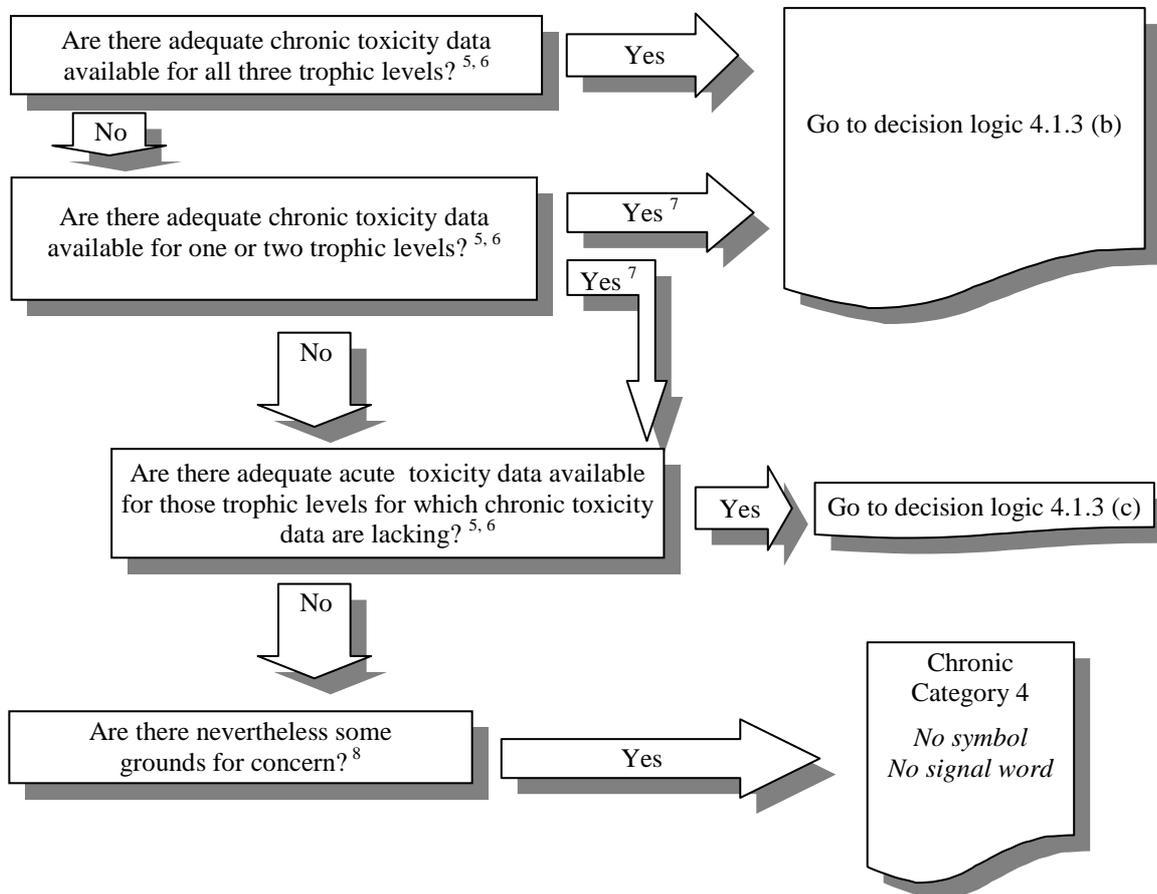
- C_i = concentration of ingredient i (weight percentage)
- $L(E)C_{50_i}$ = LC_{50} or EC_{50} for ingredient i, in mg/l
- n = number of ingredients, and i is running from 1 to n
- $L(E)C_{50_m}$ = $L(E)C_{50}$ of the part of the mixture with test data



Value to mixture
decision logic 4.1.1

4.1.5.2 Long-term aquatic hazard classification

4.1.5.2.1 Decision logic 4.1.3 (a) for substances



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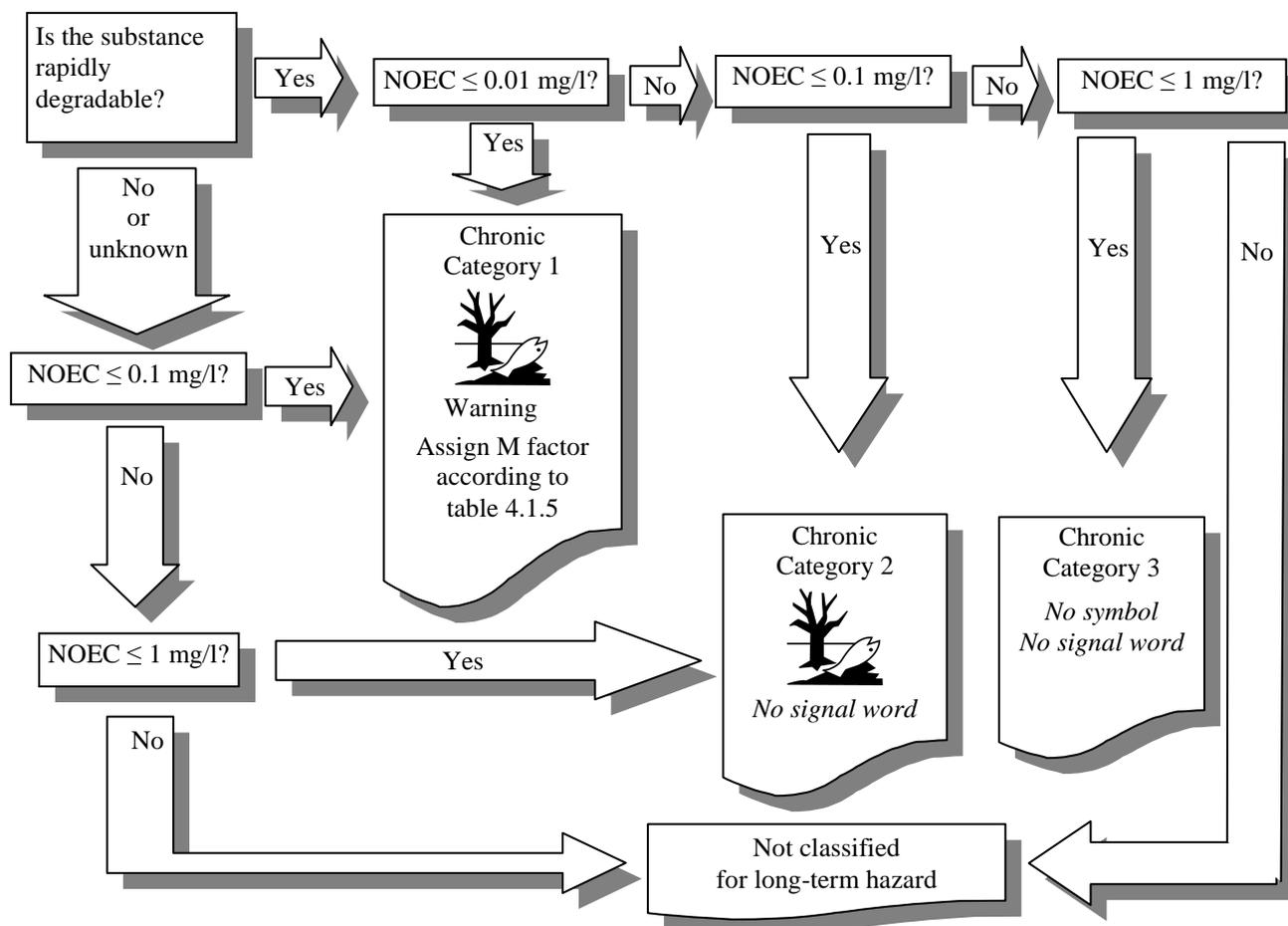
⁵ Data are preferably to be derived using internationally harmonized test methods (e.g. OECD Test Guidelines or equivalent) according to the principles of good laboratory practices (GLP), but data from other test methods such as national methods may also be used where they are considered as equivalent (see 4.1.1.2.2 and A9.3.2 of Annex 9).

⁶ See Figure 4.1.1.

⁷ Follow the flowchart in both ways and choose the most stringent classification outcome.

⁸ Note that the system also introduces a “safety net” classification (referred to as Category: Chronic 4) for use when the data available do not allow classification under the formal criteria but there are nevertheless some grounds for concern.

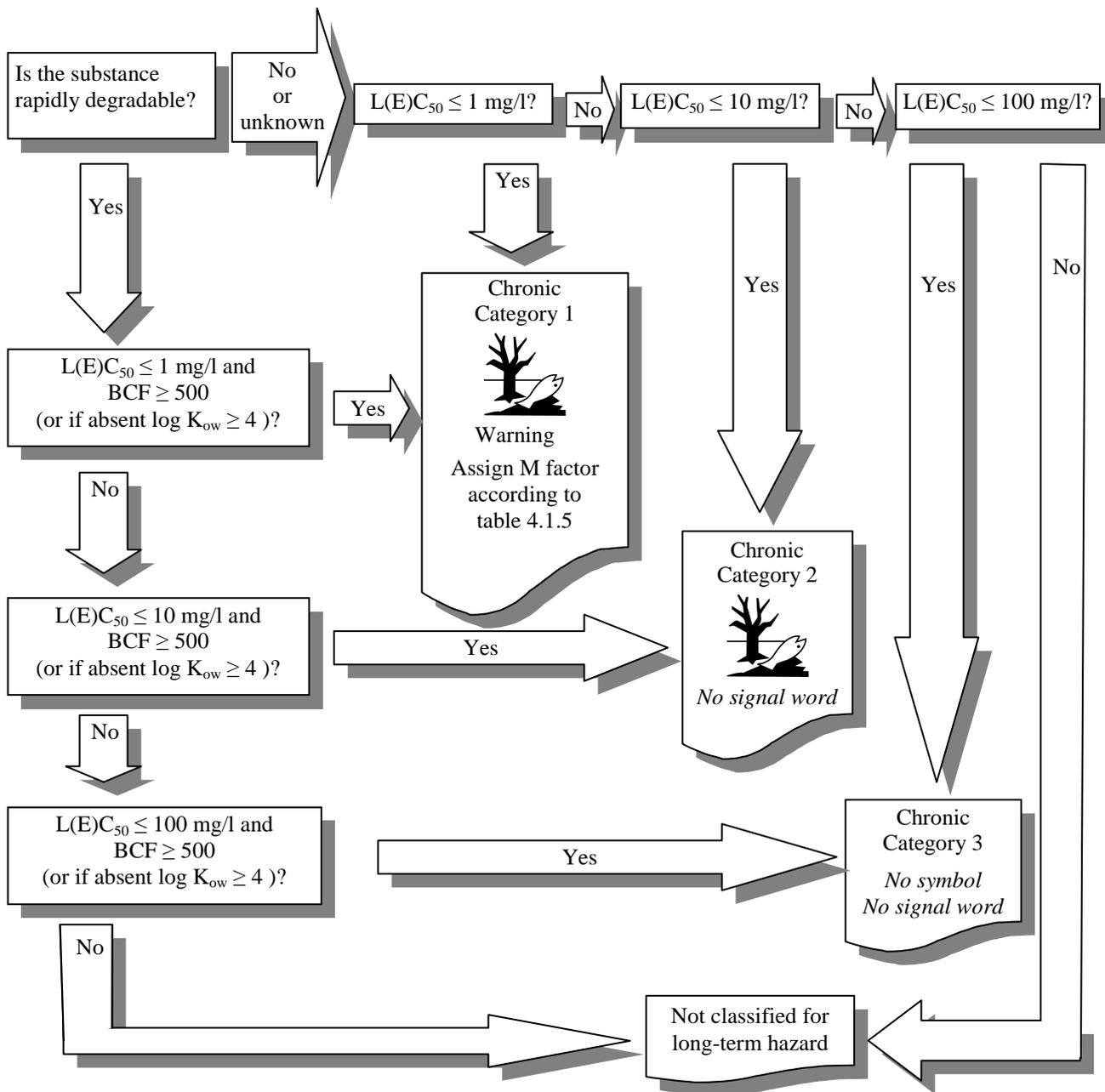
4.1.5.2.2 Decision logic 4.1.3 (b) for substances (when adequate chronic toxicity data are available for all three trophic levels)⁵



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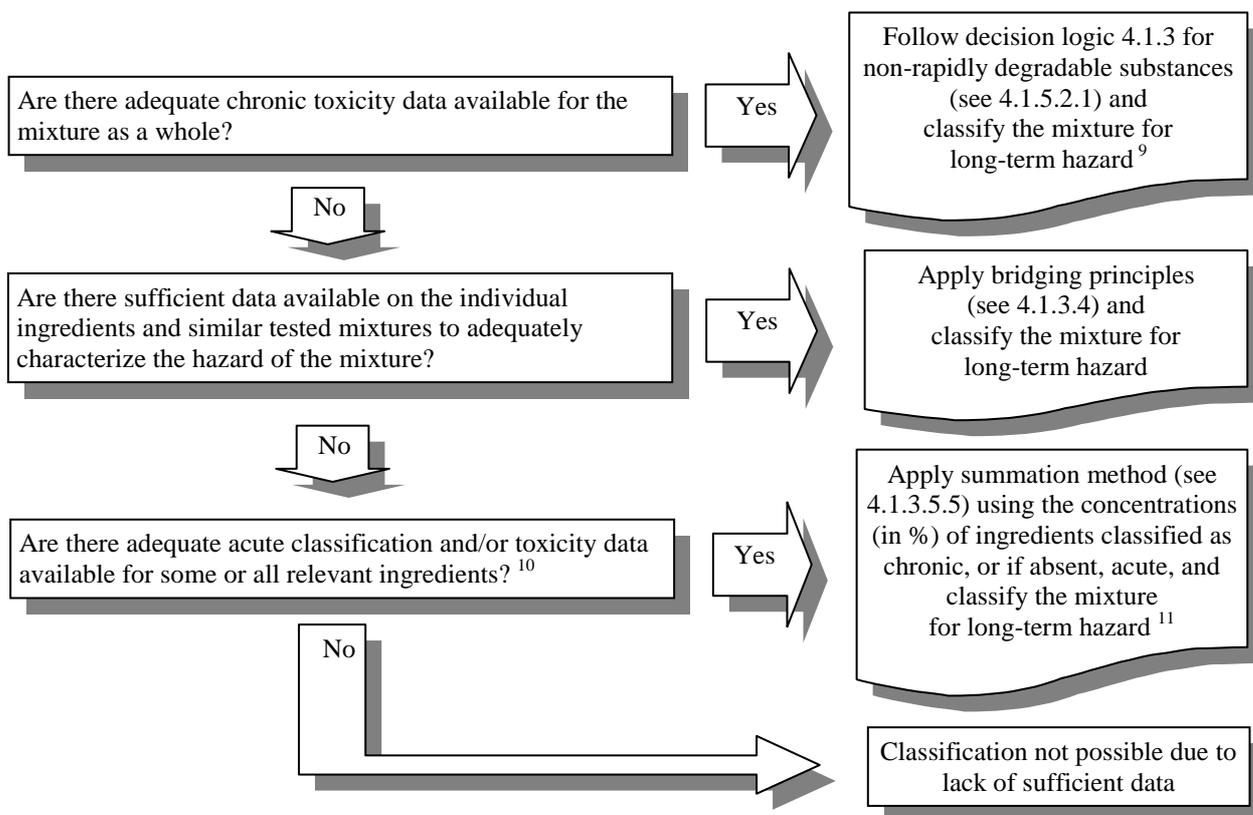
⁵ Data are preferably to be derived using internationally harmonized test methods (e.g. OECD Test Guidelines or equivalent) according to the principles of good laboratory practices (GLP), but data from other test methods such as national methods may also be used where they are considered as equivalent (see 4.1.1.2.2 and A9.3.2 of Annex 9).

4.1.5.2.3 Decision logic 4.1.3 (c) for substances (when adequate chronic toxicity data not are available for all three trophic levels)⁵



⁵ Data are preferably to be derived using internationally harmonized test methods (e.g. OECD Test Guidelines or equivalent) according to the principles of good laboratory practices (GLP), but data from other test methods such as national methods may also be used where they are considered as equivalent (see 4.1.1.2.2 and A9.3.2 of Annex 9).

4.1.5.2.4 Decision logic 4.1.4 for mixtures



⁹ Degradability and bioaccumulation tests for mixtures are not used as they are usually difficult to interpret, and such tests may be meaningful only for single substances. The mixture is therefore by default regarded as non-rapidly degradable. However, if the available information allows the conclusion that all relevant ingredients of the mixture are rapidly degradable) the mixture can, for classification purposes, be regarded as rapidly degradable.

¹⁰ In the event that no useable information on acute and/or chronic aquatic toxicity is available for one or more relevant ingredients, it is concluded that the mixture cannot be attributed (a) definitive hazard category(ies). In this situation the mixture should be classified based on the known ingredients only, with the additional statement that: “× % of the mixture consists of ingredient(s) of unknown hazards to the aquatic environment”.

¹¹ When adequate toxicity data are available for more than one ingredient in the mixture, the combined toxicity of those ingredients may be calculated using the additivity formulas (a) or (b) in 4.1.3.5.2 depending on the nature of the toxicity data. The calculated toxicity may be used to assign that portion of the mixture an acute or chronic hazard category which is then subsequently used in applying the summation method. (It is preferable to calculate the toxicity of this part of the mixture using for each ingredient a toxicity value that relate to the same taxonomic group (e.g. fish, crustacea or algae) and then to use the highest toxicity (lowest value) obtained (i.e. use the most sensitive of the three groups) (see 4.1.3.5.3)).

Chapter 4.2

Add a new chapter 4.2 to read as follows:

**“CHAPTER 4.2
HAZARDOUS TO THE OZONE LAYER**

4.2.1 Definitions

Ozone Depleting Potential (ODP) is an integrative quantity, distinct for each halocarbon source species, that represents the extent of ozone depletion in the stratosphere expected from the halocarbon on a mass-for-mass basis relative to CFC-11. The formal definition of ODP is the ratio of integrated perturbations to total ozone, for a differential mass emission of a particular compound relative to an equal emission of CFC-11.

Montreal Protocol is the Montreal Protocol on Substances that Deplete the Ozone Layer as either adjusted and/or amended by the Parties to the Protocol.

4.2.2 Classification criteria¹

A substance or mixture shall be classified as Category 1 according to the following table:

Table 4.2.1: Criteria for substances and mixtures hazardous to the ozone layer

Category	Criteria
1	Any of the controlled substances listed in Annexes to the Montreal Protocol; or Any mixture containing at least one ingredient listed in the Annexes to the Montreal Protocol, at a concentration $\geq 0.1\%$

4.2.3 Hazard communication

General and specific considerations concerning labelling requirements are provided in *Hazard Communication: Labelling* (Chapter 1.4). Annex 2 contains summary tables about classification and labelling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

¹ The criteria in this chapter are intended to be applied to substances and mixtures. Equipment, articles or appliances (such as refrigeration or air conditioning equipment) containing substances hazardous to the ozone layer are beyond the scope of these criteria. Consistent with 1.1.2.5 (a)(iii) regarding pharmaceutical products, GHS classification and labelling criteria do not apply to medical inhalers at the point of intentional intake.

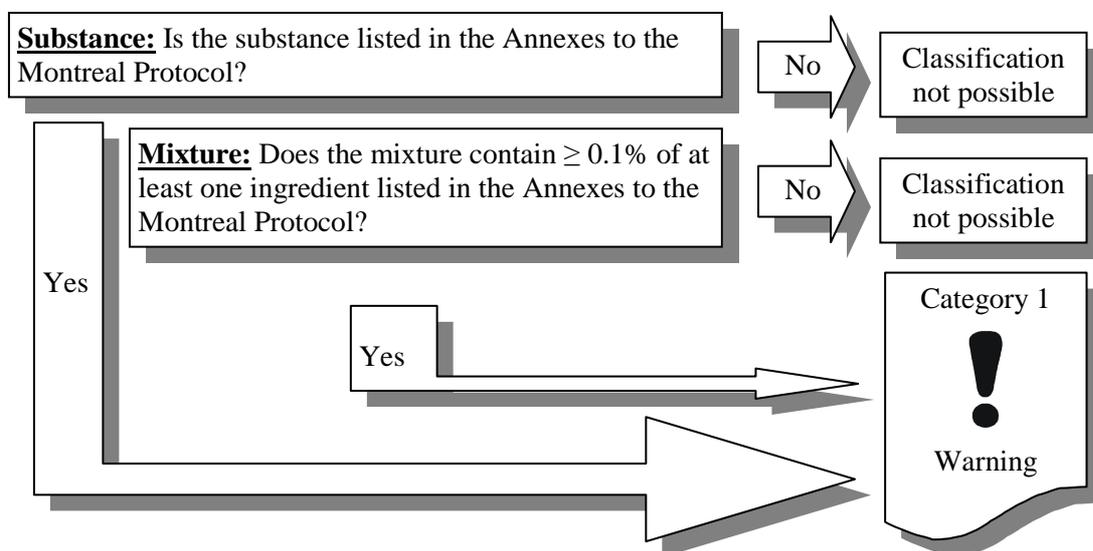
Table 4.2.2 Label elements for substances and mixtures hazardous to the ozone layer

	Category 1
Symbol	Exclamation mark
Signal word	Warning
Hazard statement	Harms public health and the environment by destroying ozone in the upper atmosphere

4.2.4 Decision logic for substances and mixtures hazardous to the ozone layer

The decision logic which follows is not part of the harmonized classification system but is provided here as additional guidance. It is strongly recommended that the person responsible for classification study the criteria before and during use of the decision logic.

Decision logic 4.2.1



ANNEXES

Annex 1

Amend the tables for respiratory and skin sensitization (page 254 of the English version) to read as follows and delete the related footnote:

RESPIRATORY SENSITIZATION				
Category 1	Category 1A	Category 1B	-	-
				
Danger	Danger	Danger		
May cause allergy or asthma symptoms or breathing difficulties if inhaled	May cause allergy or asthma symptoms or breathing difficulties if inhaled	May cause allergy or asthma symptoms or breathing difficulties if inhaled		
<p>Not required under the <i>UN Recommendations on the Transport of Dangerous Goods, Model Regulations.</i></p>				

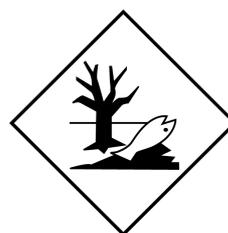
SKIN SENSITIZATION				
Category 1	Category 1A	Category 1B	-	-
				
Warning	Warning	Warning		
May cause an allergic skin reaction	May cause an allergic skin reaction	May cause an allergic skin reaction		
<p>Not required under the <i>UN Recommendations on the Transport of Dangerous Goods, Model Regulations.</i></p>				

Insert the following table at the end of current text in Annex 1:

HAZARDOUS TO THE OZONE LAYER				
Category 1	-	-	-	-
 Warning Harms public health and the environment by destroying ozone in the upper atmosphere				
Not required under the UN Recommendations on the Transport of Dangerous Goods, Model Regulations.				

In the tables for the allocation of label elements for the hazards to the aquatic environment (page 259 of the English version):

- In the headings of the tables, replace “AQUATIC TOXICITY (ACUTE)” and “AQUATIC TOXICITY (CHRONIC)” with “AQUATIC HAZARD (ACUTE)” and “AQUATIC HAZARD (LONG-TERM)”;
- For Categories 1 and 2, replace the current GHS pictograms and the mark required under the UN Model Regulations, with the following ones:



Annex 2

- A2.18 For Categories 1 and 2, in paragraph 1 (b), replace “Structure/activity or structure property” with “Structure-activity”.
- A2.19 For Categories 1 and 2, in paragraph 1 (c), replace “Structure/activity or structure property” with “Structure-activity”.

A2.20 For Category 1:

- In paragraph 1 (a): replace “human evidence that the individual substance leads” with “evidence in humans that the substance can lead”;
- In paragraphs 3 (a)(i) and (b)(i), amend the text between brackets to read as follows: (see note to Table 3.4.5)”;
- In paragraphs 3 (a)(ii) and (b)(ii), delete the text between brackets;

Add the following columns and rows:

Hazard sub-category	Criteria	Hazard communication elements	
1A (where data are sufficient and where required by a competent authority)	1. <i>For substances and tested mixtures</i> showing a high frequency of occurrence in humans; or a probability of occurrence of a high sensitization rate in humans based on animal or other tests. Severity of reaction may also be considered. 2. <i>If data for the complete mixture are not available,</i> apply bridging principles (see 3.4.3.2). 3. <i>If bridging principles do not apply,</i> classify the mixture as respiratory sensitizer if it contains at least one ingredient classified as sub-category 1A at the following concentrations: (a) Solids or liquids: $\geq 0.1\%$ w/w (b) Gases: $\geq 0.1\%$ v/v	Symbol	
		Signal word	Danger
		Hazard statement	May cause allergy or asthma symptoms or breathing difficulties if inhaled
1B (where data are sufficient and where required by a competent authority)	1. <i>For substances and tested mixtures</i> showing a low to moderate frequency of occurrence in humans; or a probability of occurrence of a low to moderate sensitization rate in humans based on animal or other tests. Severity of reaction may also be considered. 2. <i>If data for the complete mixture are not available,</i> apply bridging principles (see 3.4.3.2). 3. <i>If bridging principles do not apply,</i> classify the mixture as respiratory sensitizer if it contains at least one ingredient classified as sub-category 1B at the following concentrations: (a) Solids or liquids: $\geq 1\%$ w/w (b) Gases: $\geq 0.2\%$ v/v	Symbol	
		Signal word	Danger
		Hazard statement	May cause allergy or asthma symptoms or breathing difficulties if inhaled

A2.21 For Category 1:

- In paragraph 3 (a), replace “see note 1 to table 3.4.1” with “see note to Table 3.4.5”; and
- In paragraph 3 (b) delete “see note 2 to Table 3.4.1”.

Add the following columns and rows:

Hazard category	Criteria	Hazard communication elements	
1A (where data are sufficient and where required by a competent authority)	1. <i>For substances and tested mixtures</i> showing a high frequency of occurrence in humans and/or a high potency in animals, which can be presumed to have the potential to produce significant sensitization in humans. Severity of reaction may also be considered. 2. <i>If data for the complete mixture are not available, apply bridging principles (see 3.4.3.2)</i> 3. <i>If bridging principles do not apply, classify the mixture as skin sensitizer if it contains at least one ingredient classified as sub-category 1A at a concentration $\geq 0.1\%$.</i>	Symbol	
		Signal word	Warning
		Hazard statement	May cause an allergic skin reaction
1B (where data are sufficient and where required by a competent authority)	1. <i>For substances and tested mixtures</i> showing a low to moderate frequency of occurrence in humans and/or a low to moderate potency in animals, which can be presumed to have the potential to produce sensitization in humans. 2. <i>If data for the complete mixture are not available, apply bridging principles (see 3.4.3.2)</i> 3. <i>If bridging principles do not apply, classify the mixture as skin sensitizer if it contains at least one ingredient classified as sub-category 1B at a concentration $\geq 1.0\%$.</i>	Symbol	
		Signal word	Warning
		Hazard statement	May cause an allergic skin reaction

A2.28 (a) and (b) Replace the current symbol with the following one:



A2.28 (b) In the title, replace “Chronic hazards” with “Long-term hazards”;

For Category 1:

replace paragraph 1 with the following text:

“1. *For substances rapidly degradable:*

- (a) $\text{NOEC} \leq 0.01 \text{ mg/l}$; or, if absent
- (b) $\text{L(E)C}_{50} \leq 1 \text{ mg/l}$ and $\text{BCF} \geq 500$ (or if absent $\log K_{ow} \geq 4$)

2. *For substances non-rapidly degradable:*

- (a) $\text{NOEC} \leq 0.1 \text{ mg/l}$; or, if absent
- (b) $\text{L(E)C}_{50} \leq 1 \text{ mg/l}$ ”

Renumber current paragraphs 2, 3 and 4 as 3, 4 and 5 respectively.

For Category 2:

replace paragraph 1 with the following text:

“1. *For substances rapidly degradable:*

- (a) $0.01 < \text{NOEC} \leq 0.1 \text{ mg/l}$; or, if absent
- (b) $1 \text{ mg/l} < \text{L(E)C}_{50} \leq 10 \text{ mg/l}$ and $\text{BCF} \geq 500$ (or if absent $\log K_{ow} \geq 4$)

2. *For substances non-rapidly degradable:*

- (a) $0.1 \text{ mg/l} < \text{NOEC} \leq 1 \text{ mg/l}$;or, if absent
- (b) $1 \text{ mg/l} < \text{L(E)C}_{50} \leq 10 \text{ mg/l}$ ”

Renumber current paragraphs 2, 3 and 4 as 3, 4 and 5 respectively.

For Category 3:

replace paragraph 1 with the following text:

“1. *For substances rapidly degradable:*

- (a) $0.1 < \text{NOEC} \leq 1 \text{ mg/l}$; or, if absent
- (b) $10 \text{ mg/l} < \text{L(E)C}_{50} \leq 100 \text{ mg/l}$ and $\text{BCF} \geq 500$ (or, if absent, $\log K_{ow} \geq 4$)

2. *For substances non-rapidly degradable:*

- $10 \text{ mg/l} < \text{L(E)C}_{50} \leq 100 \text{ mg/l}$ ”

Renumber current paragraphs 2, 3 and 4 as 3, 4 and 5 respectively.

A2.29 Insert the following new table at the end of current annex 2:

“A2.29 Hazard to the ozone layer

Hazard category	Criteria	Hazard communication elements	
1	1. <i>For substances</i> Any of the controlled substances listed in the Annexes to the Montreal Protocol	Symbol	
	2. <i>For mixtures</i>	Signal word	Warning
	Any mixture containing at least one ingredient listed in the Annexes to the Montreal Protocol, at a concentration $\geq 0.1\%$	Hazard Statement	Harms public health and the environment by destroying ozone in the upper atmosphere

Annex 3

Section 1

A3.1.2.3 and A3.1.2.4 Add the following two new paragraphs:

“A3.1.2.3 In addition to individual hazard statements, a number of combined hazard statements are given in Table A3.1.2. The alphanumerical codes for the combined statements are constructed from the codes for the individual statements that are combined, conjoined with the plus (“+”) sign. For example, H300 + H310 indicates that the text to appear on the label is “Fatal if swallowed or in contact with skin”.

A3.1.2.4 All assigned hazard statements should appear on the label unless otherwise specified in 1.4.10.5.3.3. The competent authority may specify the order in which they appear. Also, where a combined hazard statement is indicated for two or more hazard statements, the competent authority may specify whether the combined hazard statement or the corresponding individual statements should appear on the label, or may leave the choice to the manufacturer/supplier.”

Table A3.1.2: For codes H317 and H334, replace “1” with “1, 1A, 1B” in column (4).

Add the following new entries after the row for H373:

H300 + H310	Fatal if swallowed or in contact with skin	Acute toxicity, oral (chapter 3.1) and acute toxicity dermal (chapter 3.1)	1, 2
H300 + H330	Fatal if swallowed or if inhaled	Acute toxicity, oral (chapter 3.1) and acute toxicity, inhalation (chapter 3.1)	1, 2
H310 + H330	Fatal in contact with skin or if inhaled	Acute toxicity, dermal (chapter 3.1) and acute toxicity, inhalation (chapter 3.1)	1, 2
H300 + H310 + H330	Fatal if swallowed, in contact with skin or if inhaled	Acute toxicity, oral (chapter 3.1), acute toxicity, dermal (chapter 3.1) and acute toxicity, inhalation (chapter 3.1)	1, 2
H301 + H311	Toxic if swallowed or in contact with skin	Acute toxicity, oral (chapter 3.1) and acute toxicity dermal (chapter 3.1)	3
H301 + H331	Toxic if swallowed or if inhaled	Acute toxicity, oral (chapter 3.1) and acute toxicity, inhalation (chapter 3.1)	3
H311 + H331	Toxic in contact with skin or if inhaled	Acute toxicity, dermal (chapter 3.1) and acute toxicity, inhalation (chapter 3.1)	3
H301 + H311 + H331	Toxic if swallowed, in contact with skin or if inhaled	Acute toxicity, oral (chapter 3.1), acute toxicity, dermal (chapter 3.1) and acute toxicity, inhalation (chapter 3.1)	3
H302 + H312	Harmful if swallowed or in contact with skin	Acute toxicity, oral (chapter 3.1) and acute toxicity dermal (chapter 3.1)	4
H302 + H332	Harmful if swallowed or if inhaled	Acute toxicity, oral (chapter 3.1) and acute toxicity, inhalation (chapter 3.1)	4
H312 + H332	Harmful in contact with skin or if inhaled	Acute toxicity, dermal (chapter 3.1) and acute toxicity, inhalation (chapter 3.1)	4
H302 + H312 + H332	Harmful if swallowed, in contact with skin or if inhaled	Acute toxicity, oral (chapter 3.1), acute toxicity, dermal (chapter 3.1) and acute toxicity, inhalation (chapter 3.1)	4
H303 + H313	May be harmful if swallowed or in contact with skin	Acute toxicity, oral (chapter 3.1) and acute toxicity dermal (chapter 3.1)	5
H303 + H333	May be harmful if swallowed or if inhaled	Acute toxicity, oral (chapter 3.1) and acute toxicity, inhalation (chapter 3.1)	5
H313 + H333	May be harmful in contact with skin or if inhaled	Acute toxicity, dermal (chapter 3.1) and acute toxicity, inhalation (chapter 3.1)	5

H303 + H313 + H333	May be harmful if swallowed, in contact with skin or if inhaled	Acute toxicity, oral (chapter 3.1), acute toxicity, dermal (chapter 3.1) and acute toxicity, inhalation (chapter 3.1)	5
H315 + H320	Causes skin and eye irritation	Skin corrosion/irritation (chapter 3.2) and serious eye damage/eye irritation (chapter 3.3)	2 (skin)/2A (eye)

Table A3.1.3:

- In column (3) replace “acute toxicity (Chapter 4.1)” with “acute hazard (Chapter 4.1)” and “chronic toxicity (Chapter 4.1)” with “long-term hazard (Chapter 4.1)”; and

- Add a new row at the end to read as follows:

H420	Harms public health and the environment by destroying ozone in the upper atmosphere	Hazardous to the ozone layer (Chapter 4.2)	1
------	--	--	---

Section 2

Table A3.2.2:

replace “1” with “1, 1A, 1B” in column (4) against each reference to chapter 3.4 in column (3); (apply to codes P261, P272, P280 and P285)

Table A3.2.3:

replace “1” with “1, 1A, 1B” in column (4) against each reference to chapter 3.4 in column (3); (apply to codes P302, P304, P311, P313, P321, P333, P341, P342, P352, P363, P302+P352, P304+P341, P333+P313 and P342+P311).

Table A3.2.5:

- replace “1” with “1, 1A, 1B” in column (4) against each reference to chapter 3.4 in column (3);
- Add a new row at the end of the table, to read as follows:

P502	Refer to manufacturer/supplier for information on recovery/recycling	Hazardous to the ozone layer (Chapter 4.2)	1	
------	---	--	---	--

Tables A3.2.2 (for P273), A3.2.3 (for P391) and A3.2.5 (for P501):

replace, in column (3), “acute toxicity (Chapter 4.1)” with “acute hazard (Chapter 4.1)” and “chronic toxicity (Chapter 4.1)” with “long-term hazard (Chapter 4.1)”.

Section 3

A3.3.5 In the matrix for respiratory and skin sensitization (pages 379 and 380 of the English version of the GHS), under “hazard category” replace “1” with “1, 1A, 1B”.

In the matrix of precautionary statements for hazardous to the aquatic environment (pages 391 to 394 of the English version):

- replace, in the title (pages 393 and 394 of the English version): “CHRONIC HAZARD” with “LONG-TERM HAZARD”;
- replace current symbols for acute hazard (category 1) and long-term hazard (categories 1 and 2) by the following:



A3.3.5.1 Add the following table at the end of section 3:

**HAZARDOUS TO THE OZONE LAYER
(Chapter 4.2)**

Symbol Exclamation mark

Hazard category	Signal word	Hazard statement	!
1	Warning	H420 Harms public health and the environment by destroying ozone in the upper atmosphere	!

Precautionary statements			
Prevention	Response	Storage	Disposal
			P502 Refer to manufacturer/supplier for information on recovery/recycling

Annex 9

- A9.1.2 In the first sentence delete “chemical” before “substances”
- A9.1.3 In the last but one sentence, delete “chemical” before “substances” and replace “aquatic toxicity” with “acute aquatic toxicity; chronic aquatic toxicity;”
- A9.1.4 Amend the first sentence to read as follows: “This annex is limited, at this stage, to the application of the criteria to substances.”.
- A9.1.5 In the first sentence, replace “aquatic toxicity” with “acute aquatic toxicity; chronic aquatic toxicity;”.
- A9.1.8 In the last sentence, replace “The three core properties, aquatic toxicity” with “The four core properties, acute and chronic aquatic toxicity”.
- A9.1.10 In (a), insert “or NOEC” after “L(E)C₅₀”.
- In (b), amend the first sentence to read as follows: “unstable substances: such substances that degrade (or react) rapidly in the test system present both testing and interpretational problems”.
- A9.1.11 In the third sentence, replace “data on aquatic toxicity” with “data on acute and on chronic aquatic toxicity”
- A9.2.1 In the French version, replace “substances chimiques” with “produits chimiques” in the first sentence (*The amendment does not apply to the English version*).
- In the fourth sentence, replace “one Acute sub-class, consisting of three categories and one sub-class, consisting of 4 categories” with “one sub-class for acute aquatic hazards, consisting of three categories and one sub-class for long-term aquatic hazards, consisting of four categories.”.
- In the last but one sentence replace “chronic hazard categories” with “long-term hazard categories”.
- A9.2.2 Replace “4.1.2.2” with “4.1.2.4” and “Figure” with “Table”.
- A9.2.3.1 In the first sentence, replace “longer-term toxicity” with “long-term toxicity”.
- In the last but one sentence, replace “chronic hazard” with “long-term hazard”.
- A9.2.3.2 In the third sentence, replace “chronic hazard” with “long-term hazard”.
- Amend the fifth and sixth sentences to read as follows:
- “It is this acute toxicity which has therefore been used as the core property in defining both the acute and the long-term hazard if no adequate chronic test data are available. Nevertheless, it has been recognized that chronic toxicity data, if available, should be preferred in defining the long-term hazard category.”
- Delete the last sentence (“The development...of the scheme”).

A9.2.3.3 Insert a new paragraph to read as follows:

“A9.2.3.3 The combination of chronic toxicity and intrinsic fate properties reflects the potential hazard of a substance. Substances that do not rapidly degrade have a higher potential for longer term exposures and therefore should be classified in a more severe category than substances which are rapidly degradable (see A9.3.3.2.2).”

Current paragraphs A9.2.3.3 to A9.2.3.6 become A9.2.3.4 to A9.2.3.7.

A9.2.3.4 (former A9.2.3.3) Amend the second sentence to read as follows:

“Substances rapidly biodegrading that show acute toxicity with a significant degree of bioaccumulation will normally show chronic toxicity at a significantly lower concentration.”.

Delete the third sentence (“Precise acute generally precautionary”).

Amend the last sentence before (a) and (b), to read as follows:

“Thus, for example, in absence of adequate chronic test data, category Chronic 1 should be assigned if either of the following criteria are met:”

A9.2.3.5 (former A9.2.3.4) Amend to read as follows:

“A9.2.3.5 The precise definitions of the core elements of this system are described in detail in sections A9.3, A9.4 and A9.5.”

A9.2.3.7 (former A9.2.3.6) In the first sentence delete “acute”.

A9.2.4.1 Amend current sub-paragraphs (a) to (g) to read as follows:

- “(a) water solubility;
- (b) acute aquatic toxicity (L(E)C_{50S});
- (c) chronic aquatic toxicity (NOECs and/or equivalent EC_x);
- (d) available degradation (and specifically evidence of ready biodegradability);
- (e) stability data, in water;
- (f) fish bioconcentration factor (BCF);
- (g) octanol/water partition coefficient (log K_{ow});”

A9.2.4.2 In the fourth sentence, insert “and the chronic aquatic toxicity is greater than 1 mg/l,” after “soluble substances”.

A9.2.4.3 Insert a new paragraph A9.2.4.3 to read as follows:

“A9.2.4.3 If chronic aquatic toxicity data are available, cut-off values will depend on whether the substance is rapidly degradable or not. Therefore, for non-rapidly degradable substances and those for which no information on degradation is available, the cut-off levels are higher than for those substances where rapid degradability can be confirmed (see Chapter 4.1, Tables 4.1.1 and 4.1.2).”.

Current paragraphs A9.2.4.3 and A9.2.4.4 become A9.2.4.4 and A9.2.4.5 respectively.

A9.2.4.4 (former A9.2.4.3) Amend the beginning of the first sentence to read as follows:

“Where the lowest acute aquatic toxicity data are below 100 mg/l and no adequate chronic toxicity data are available, it is necessary...”.

In the third sentence, replace “chronic hazard” with “long-term hazard”.

In the last but one sentence, replace “chronic hazard class” with “long-term hazard category”

Amend the last sentence to read as follows:

“If the substance is both rapidly degradable and has a low potential to bioaccumulate ($BCF < 500$ or, if absent $\log K_{ow} < 4$) then it should not be assigned to a long-term hazard category, unless the chronic toxicity data indicate otherwise (see A9.2.4.3).”.

A9.2.6.3 In the seventh sentence, replace “chronic hazard class” with “long-term hazard category”.

A9.3.2.2 In the paragraph starting with “Chronic testing” insert “generally” before “involves”.

Add the following paragraph at the end, after the second paragraph in italics:

“An OECD document describes the main statistical methods for the analysis of data of standardized ecotoxicity tests (OECD 2006).”

A9.3.2.7.1 Amend the first sentence of the second paragraph to read as follows:

“The algal test is a short-term test that provides both acute and chronic endpoints.”

A9.3.3.2.1 In the first sentence, replace “potential or actual properties” with “intrinsic property”.

A9.3.3.2.2 Insert a new paragraph A9.3.3.2.2 to read as follows:

“A9.3.3.2.2 For the classification based on chronic toxicity a differentiation is made between rapidly degradable and non-rapidly degradable substances.

Substances that do rapidly degrade are classified in category Chronic 1 when a chronic toxicity determined to be ≤ 0.01 mg/l. Decimal bands are accepted for categorizing chronic toxicity above this category. Substances with a chronic toxicity measured from 0.01 to 0.1 mg/l are classified in category Chronic 2 for chronic toxicity, from 0.1 to 1.0 mg/l are classified in category Chronic 3 for chronic toxicity, and those over 1.0 mg/l are regarded as practically non-toxic. For substances that do not rapidly degrade or where no information on rapid degradation is available two chronic categories are used: Chronic 1 when a chronic toxicity determined to be ≤ 0.1 mg/l and Chronic 2 when chronic toxicity is measured from 0.1 to 1.0 mg/l.”

Current paragraphs A9.3.3.2.2 and A9.3.3.2.3 become new paragraphs A9.3.3.2.3 and A9.3.3.2.4, respectively.

A9.3.3.2.3 (former A9.3.3.2.2) Amend to read as follows:

“A9.3.3.2.3 Since chronic toxicity data are less common in certain sectors than acute data, for classification schemes, the potential for chronic toxicity is, in absence of adequate chronic toxicity data, identified by appropriate combinations of acute toxicity, lack of degradability and/or the potential or actual bioaccumulation. However, where adequate chronic toxicity data exist, this shall be used in preference over the classification based on the combination of acute toxicity with degradability and/or bioaccumulation. In this context, the following general approach should be used:

- (a) If adequate chronic toxicity data are available for all three trophic levels this can be used directly to determine an appropriate chronic hazard category;
- (b) If adequate chronic toxicity data are available for one or two trophic levels, it should be examined if acute toxicity data are available for the other trophic level(s). A potential classification is made for the trophic level(s) with chronic data and compared with that made using the acute toxicity data for the other trophic level(s). The final classification shall be made according to the most stringent outcome;
- (c) In order to remove or lower a chronic classification using chronic toxicity data, it must be demonstrated that the NOEC(s) (or equivalent EC_x) used would be suitable to remove or lower the concern for all taxa which resulted in classification based on acute data in combination with degradability, and/or bioaccumulation. This can often be achieved by using a long-term NOEC for the most sensitive species identified by the acute toxicity. Thus, if a classification has been based on a fish acute LC_{50} , it would generally not be possible to remove or lower this classification using a long-term NOEC from an invertebrate toxicity test. In this case, the NOEC would normally need to be derived from a long-term fish test of the same species or one of equivalent or greater sensitivity. Equally, if classification has resulted from the acute toxicity to more than one taxa, it is likely that NOECs from each taxa will be needed. In case of classification of a substance as Chronic 4,

sufficient evidence should be provided that the NOEC or equivalent EC_x for each taxa is greater than 1 mg/l or greater than the water solubility of the substances under consideration.”

A9.3.3.2.4 (former A9.3.3.2.3) In the first paragraph:

- replace “de-classifying chemicals” with “removing or lowering a classification” and “(1)”, “(2)” and “(3)” with “(a)”, “(b)” and “(c)” respectively;
- replace “end points” with “acute endpoints” at the end.

In the second paragraph, after “taxonomic group is”, insert “in the toxicity band corresponding to a less stringent classification category or” and replace “declassification” with “removing or lowering a classification”.

A9.3.3.2.4 Delete.

A9.3.5.1 In the third sentence, delete “chemical” before “substances”.

A9.3.5.4 In the second sentence, replace “Where toxicities” with “Where acute toxicities”; in the third sentence replace, “if the estimated toxicity is >” with “if the estimated acute toxicity is greater than” and in the fifth sentence, replace “when toxicity is estimated to be >” with “when acute toxicity is estimated to be greater than”.

A9.3.5.7.2 (d) Delete the second sentence (“In principle...be considered”).

A9.3.5.8 (a) and (c) Insert “or NOEC” after “L(E)C₅₀”.

A9.4.1.1 In the first sentence of the first and second paragraphs, delete “chemical” before “substances”.

A9.4.2.1 In the first sentence delete “chemical” before “substances” and in the last sentence replace “A9.2.3.3” with “A9.2.3.3” and “4.1.2.10.3” with “4.1.2.11.3”.

A9.4.2.2.3 At the beginning of the first paragraph, insert “(see 4.1.2.10.3)” after “The harmonized criteria”.

Add a new paragraph to read as follows:

“Where there is sufficient justification, the 10-day window condition may be waived for complex, multi-component substances and the pass level applied at 28 days. The constituents of such substances may have different chain-lengths, degree and/or site of branching or stereo-isomers, even in their most purified commercial forms. Testing of each individual component may be costly and impractical. If a test on the complex, multi-component substance is performed and it is anticipated that a sequential biodegradation of the individual structures is taking place, then the 10-day window should not be applied to interpret the results of the test. A case by case evaluation should however take place on whether a biodegradability test on such a substance would give valuable information regarding its

biodegradability as such (i.e. regarding the degradability of all the constituents) or whether instead an investigation of the degradability of carefully selected individual components of the complex, multi-component substance is required.”.

A9.4.2.4.1 and A9.4.2.4.2 Replace “4.1.2.10.3” with “4.1.2.11.3”.

A9.4.3.2.2 In the first sentence delete “chemical” before “substances”

A9.5.1.1 In the first and third sentences delete “chemical” before “substances”

A9.5.1.2, A9.5.2.1, A9.5.3.2.1 and A9.7.1.1 In the first sentence delete “chemical” before “substances”

A9.5.2.3.8.3 Replace “Figure” with “Table”

Annex 9, Appendix I

3.7.1 and 3.8.1 Delete “chemical” before “substances”.

Annex 9, Appendix VI

Add the following reference in section 1 “Aquatic toxicity” (page 535 of the English version):

“OECD 2006. “Current approaches in the statistical analysis of ecotoxicity data: A guidance to application”, OECD Environment Health and Safety Publications Series Testing and Assessment N.54.”

Annex 10

A10.5.1.1 Add the following sentence at the end of sub-paragraph (e):

“acrodisc filter should be flushed at least three times with fresh medium to avoid elevated trace metals in sample at time 0;”

In sub-paragraph (f), replace “+ 2°C within the temperature range 20°C to 25°C” with “± 1.5°C in the range 20-23°C”

Amend sub-paragraph (k) to read as follows:

“Analytical equipment for metal analysis (e.g. atomic adsorption spectrometry, inductively coupled axial plasma spectrometry) of acceptable accuracy, preferably with a limit of quantification (LOQ) five times lower than the lowest chronic ecotoxicity reference value;”

A10.5.1.3 In the last sentence, insert “or higher” before “pH”.

A10.5.1.7 In the second paragraph, insert “and up to pH 8 and 8.5” after “pH 7 and 6”.

Table A10.1 Amend to read as follows:

“Table A10.1: Recommended chemical composition of testing medium

Chemical composition of medium	NaHCO ₃	6.5 mg/l	12.6 mg/l	64.75 mg/l	194.25 mg/l
	KCl	0.58 mg/l	2.32 mg/l	5.75 mg/l	5.74 mg/l
	CaCl ₂ ·2H ₂ O	29.4 mg/l	117.6 mg/l	294 mg/l	29.4 mg/l
	MgSO ₄ ·7H ₂ O	12.3 mg/l	49.2 mg/l	123.25 mg/l	123.25 mg/l
CO ₂ concentration (balance is air) in test vessel		0.50%	0.10%	0.038% (air)	0.038% (air)
Calculated pH		6.09	7.07	7.98	8.5

Add a new note to table A10.1 to read as follows:

“NOTE 2: While the protocol was only validated for the pH range 6.0-8.0, this table does not prevent attaining pH 5.5. Composition for pH 8.5 has not been verified experimentally in presence of metal.”

Current “NOTE” becomes “NOTE 1”.

A10.5.1.8 Add a new sentence at the end to read as follows:

“pH should not be adjusted during the test using an acid or alkali.”

A10.5.2.3.3 In the second paragraph:

- In the first sentence replace “± 2°C in the range 20-25°C” with “± 1.5°C in the range 20-23°C”.
- In the last sentence, replace “the solution is acidified with 1% HNO₃ and analyzed” with “the solution is acidified with one or two drops of trace metal grade HNO₃ with the target pH 1 and analyzed”.

A10.5.2.3.5 Insert a new paragraph A10.5.2.3.5 with the following text:

“To ensure reproducibility of transformation data, it is recommended that:

- (a) new laboratories use a training set;
- (b) one metal powder with specified surface conditions be used as standard control; and
- (c) one or two laboratories be responsible for reference chemicals.

It may be necessary to check specific surface areas of the powders.”

A10.5.4.1 Replace “± 2°C in the range 20-25°C” with “± 1.5°C in the range 20-23°C”.

A10.5.4.3 Amend the end of the first sentence to read as follows: “maintain the dissolved oxygen concentration above about 6.0 mg/l, which is 70% of the saturation level of 8.5 mg/l”.
